



TGA

THERAPEUTIC GOODS ADMINISTRATION



TGA e-Business Application Lodgement User Reference Workbook Medical Devices

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NAVIGATION

Medical Device – Home Page

The Medical Device section of the TGA e-Business system enables you to submit a range of Device Applications electronically.

The e-Business system allows you to:

Submit Manufacturers Evidence ([Manufacturers Evidence](#))

Create a Variation to - ([Accepted Medical Device Evidence](#))

Submit a Device Change Request ([Request Change](#))

Apply for a Conformity Assessment Certificate ([Conformity Assessment](#))

Make a Variation to a Class II/AIMD Device ([Class III/AIMD Variation](#))

Lodge a Device Application ([Device Application](#))

View/Print ARTG Certificates ([TGA Information](#))



Screen Buttons

The following series of buttons can be found at the top and bottom of the e-Business screens. They are used to navigate through, or initiate an action within an e-Business application.

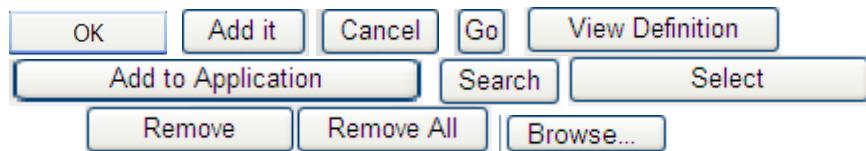
[Previous](#) [Next](#) [Close](#) [Save](#) [View Entire App](#) [Validate](#)

The following series of buttons can be found within the e-Business search screens. They are used to initiate an action related to a field .



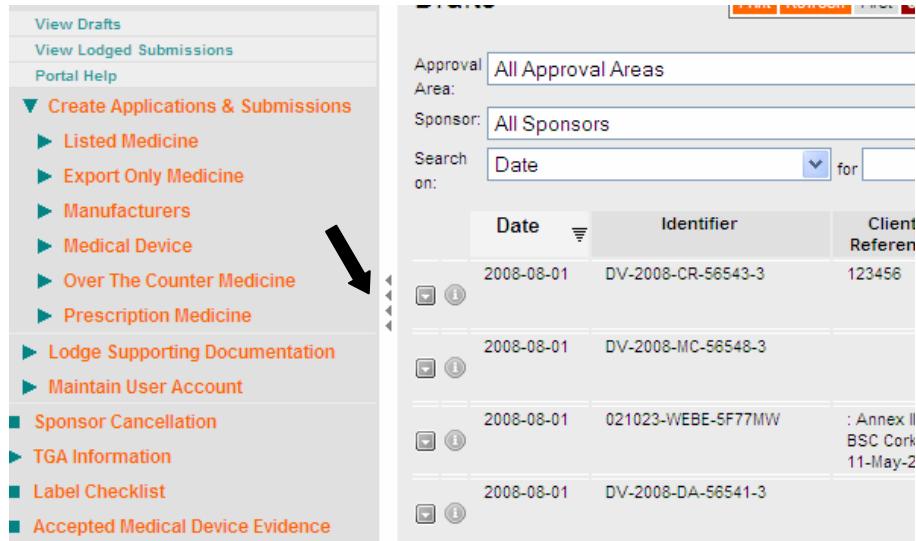
Search Screen Buttons

The following series of buttons are found within search screens in the e-Business system. They are used to initiate an action within that particular search screen.



Screen Adjustment

At the home page, between the menu and the screen view there are sets of triangular shaped symbols.



Date	Identifier	Client Reference
2008-08-01	DV-2008-CR-56543-3	123456
2008-08-01	DV-2008-MC-56548-3	
2008-08-01	021023-WEBC-5F77MW	: Annex II BSC Cork 11-May-2
2008-08-01	DV-2008-DA-56541-3	

When you click on these symbols, the right hand screen view will expand to fill the entire screen. This may be of use when filling out electronic forms on the TGA ebusiness system.

ARTG Clone Search Buttons

These buttons are found within the ARTG Clone search screen. They are used to navigate or initiate an action.





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Mandatory Fields

A number of fields within the TGA e-Business system are mandatory. These mandatory fields are indicated with a 'red star' (*). If you miss filling out one of these mandatory fields, your e-Business application will not complete until the mandatory field is filled.

Help

There are different forms of help available in the TGA e-Business System.

- Portal help [Portal Help](#)
- Page help [Help](#)
- Question help [?](#)
- User documentation

Portal Help is found in the drop down list menu under your user name on the TGA e-Business home page. It contains help on navigating around the e-Business screens.

Page help will give an outline of the information required within the page.

Question help gives an explanation where a question has been asked.

User documentation provides a step by step guide to eBS from a Medical Device perspective and is located under Training and then the Documentation link off the main menu drop down list.

MANUFACTURERS EVIDENCE

Prior to making a Device Application for:

- An Included Medical Device (except for Class 1);
- Other Therapeutic Goods – Registered - IVD and
- Other Therapeutic Goods – Listed - IVD.

the Manufacturers Evidence screen needs to be completed. The details entered on Manufacturers Evidence should demonstrate to the TGA that the correct Conformity Assessment steps have been taken to confirm the presence of a Quality Management System.

Manufacturers Evidence - Page 1

NOTE:

(Click on the  for an explanation of the current screen or field)

(Click on the  for an explanation of a question)

An [Application Identifier](#) will be generated automatically when you save, close, validate, or go to the next page of the form.

A number of the fields will generate automatic information. This is based on your Log-In details. (Ie – Sponsor Details, address etc)

[Agent Details](#) will only be displayed if you are logged in as an Agent.

To Commence Manufacturer's Evidence

Select [Portal – Therapeutic Goods Administration](#)

When the screen drops down

Select [Create Applications and submissions](#)

Select [Medical Device](#)

then

Click on [Manufacturer Evidence](#) to open the link

TGA eBS Manufacturer Evidence

Page 1

Evidence Identifier: Will be generated on save.
Version No: 1 (New Notification)

Notification Details

★ Sponsor's own reference:

Sponsor Details

Agent name: TGA Demo A
Sponsor ID: TGA Demo A
Contact name: Device Demo
Contact email: DeviceDemo@tga.com.au

Certification Details

★ Certification issued under:

Search **Remove**

The manufacturer name for a manufacturer evidence notification can only be selected from the list accessed by the 'Search' function. You will not be able to submit this notification without a valid manufacturer name. Where your manufacturer name is not in the list, please use the "New Manufacturer" function to apply for its entry in the TGA Client database.

New Manufacturer

New Notification

Notification Details

At the Field **Sponsor's Own Reference**:

enter your own reference details (this can help you to identify your own manufacturers evidence)

Page 1

New Notification

Notification Details

★ Sponsor's Own Reference:

Sponsor Details

At the Field **Sponsor ID**:

If you are logged in as a sponsor -
your Sponsor ID will be automatically selected (based on your log-In);
Or

If you are logged in as an agent -
you will need to make a selection from the drop down Sponsor ID list

Notification Details

★ Sponsor's own reference:

Sponsor Details

Agent name: TGA Demo A
Sponsor ID: TGA Demo Spo
Contact name: TGA Demo A
Contact email: TGA Demo Spo.m.au

Certification Details

★ Certification issued under:

The **Contact Name** and **Contact Email** will be automatically generated when you log-in.



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★ Sponsor ID:	TGA Demo Spo
★ Contact name:	Device Demo
Contact email:	Devidedemo@tga.com.au

Certification Details

This field relates to the legislation the certificate was issued in accordance with (eg Council Directive 93/42EEC (MDD)). Your selection here sets up the page format for the remainder of this screen. (*Selecting IVD/OTG Quality System Certification results in a slightly different screen – see alternative notes*)

At the field

Certification Issued Under:

Select your relevant option from the drop down list.

Certification Details ★ Certification Issued Under: ★ Manufacturer Name: <input type="button" value="Search"/> <input type="button" value="Remove"/>		... Please Select Please Select ... Council Directive 90/385/EEC (AIMD) Council Directive 93/42/EEC (MDD) IVD/OTG Quality System Certification MRA Compliance Certification System or Procedure Pack DOC TGA Certification
New Manufacturer Name: New Manufacturer Address: New Manufacturer Country:	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	

Enter details for an Existing Manufacturer

At the field **Manufacturer Name:**

You will need to search for the correct Manufacturer of your device.

Click on the button

The following search screen will appear

Search: <input type="text"/> <input type="button" value="Search"/> - Keywords including AND and OR may be used to refine your search. - Use * (wildcard) when searching on incomplete words. Enter a search... <input type="button" value="Add to Application"/> <input type="button" value="Cancel"/>
--

Search for your manufacturer by typing in the name or first few letters of the name (In this instance her) Then click on the Search button

Search: <input type="text"/> <input type="button" value="Search"/> - Keywords including AND and OR may be used to refine your search. - Use * (wildcard) when searching on incomplete words.
--

A list of recognised Manufacturers with the letters 'her' in the title will be listed.

Search:

- Keywords including AND and OR may be used to refine your search.
- Use * (wildcard) when searching on incomplete words.

Healthy Heroes Inc (Australia) [46789]
Herculies Hormones (Greece) [34980]
Hermone Hex (Ireland) [67589]
Hermans Hermit Habit (England) [86543]

Select your Manufacturer by pointing to it and clicking. This will highlight the Manufacturer

Healthy Heroes Inc (Australia) [46789]
Herculies Hormones (Greece) [34980]
Hermone Hex (Ireland) [67589]
Hermans Hermit Habit (England) [86543]

Once you have selected your Manufacturer,

Click on

If you make an incorrect selection and need to make a different selection,

Click on

This will return you to the Notification of Manufacturer's Conformity Assessment screen where you can commence your search again.

This will take your selection and insert it in the **Manufacturer Name** field
on the Manufacturers Evidence screen.

It will also automatically enter the Manufacturer Address in the **Manufacturer Address as on Evidence:** field

NOTE:

There may be more than one address for this manufacturer – the address used here should be the address that is supplied with any supporting evidence for the submission.

If you make a mistake or need to make a different selection,

Click on

This will clear the Manufacturers details from the screen where you can commence your search again.



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Enter Details for a New Manufacturer

If the manufacturer is new (does not appear on the TGA Client Database) you will need to add the Manufacturer details.

Click on **New Manufacturer**

The following screen will appear.

Request for entry of a new manufacturer on the TGA Client database

This email new manufacturer request facility will be sent to the corporate management area of TGA for entry of the manufacturer name and address details into the TGA Client database. The attached or supporting information will be used to help resolve duplicate names or other administrative anomalies. A return email will be used to help resolve any name and address concerns.

The request is for
Contact person
Email
New manufacturer name:
Manufacturer address:
Country:

Please attach documentation containing the name and address details to support the administrative request. Up to three separate attachments can be added to this form, but only one is mandatory.

You should save your manufacturer evidence notification as a draft till notified that your new manufacturer has been entered into the TGA Client database. You will receive a return email indicating the name is available for use in your evidence notification.

You will need to type in

The New Manufacturer Name
The New Manufacturer Address, and
Select the Manufacturer Country from the drop down list.

You will need to provide documents proving the manufacturer address details. These can be attached electronically.

Click on **Browse...**

This will access your own computer system where you can select the relevant documents relating to the manufacturer. The documents will be added to the Request for entry of a new manufacturer on the TGA Client Database.

Once you have completed filling out the new manufacturer details, you should print a copy of your request.

Click on **Print**

And follow the prompts to print the request.

Once you have printed your request, you can then forward it to the TGA.



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Click on **Send**

This takes you back to page 2A of your Device Application.

At this point, you should **Save** and **Close** your application. Until the new manufacturer details are acknowledged by the TGA, you will not be able to submit the manufacturer evidence (new notification). You should receive an e-mail from the TGA confirming the receipt of your New Manufacturer details.

Take note of your Application Identifier Number for accessing your draft manufacturer evidence (new notification) once your new manufacturer has been included on the TGA database.

At a later date, you will receive an e-mail from the TGA advising that the new manufacturer has been added to the database. You will then be able to access your draft, add the manufacturer then continue with your application.

Class of Device(s):

Select the **Class of Device(s):**
by clicking the relevant box

★ Class of Device(s):	?	<input type="checkbox"/> AIMD
		<input type="checkbox"/> Class 1 Measurement
		<input checked="" type="checkbox"/> Class 1 Sterile
		<input type="checkbox"/> Class IIa
		<input type="checkbox"/> Class IIb
		<input type="checkbox"/> Class III

You can select more than one class.

Conformity Assessment Procedure

Select a relevant Schedule from the drop down list at the **Conformity Assessment Procedure:** field.

★ Conformity Assessment Procedure:	?	<input type="button" value="Schedule 3 Part 3 (Annex IV)"/>	
★ Assessment Body:		<input type="button" value="-- Please Select --"/>	
Issuer's File Reference Number:		<input type="button" value="Schedule 3 Part 1 (Annex II)"/>	
Issuer Certificate Number:		<input type="button" value="Schedule 3 Part 4 (Annex V)"/>	
★ Evidence Issue Date:	(dd/mm/yyyy)	<input type="button" value="Schedule 3 Part 5 (Annex VI)"/>	
Evidence Expiry Date:	(dd/mm/yyyy)	<input type="button" value="Schedule 3 Part 6 (Annex VII)"/>	
		<input type="button" value="Schedule 3 Part 7 Clause 7.5"/>	
		<input type="button" value="Schedule 3 Part 7 (Annex VIII)"/>	

Assessment Body

At **Assessment Body:** Select from the drop down list, the organisation that carried out the QMS certification.

★ Assessment Body:	<input type="button" value="-- Please Select --"/>	
---------------------------	--	--

Type in
Issuer's File Reference Number



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(This would be the specific number for your device, allocated by the Issuing Authority)

Type in the
[Issuer Certificate Number](#)

Type in the
[Evidence Issue Date:](#)

Note: If left blank, the Evidence Expiry Date will default to 5 years from the Evidence Issue Date.

Type in the
[Evidence Expiry Date:](#)

Click on at the top or bottom of the screen.

This will initiate an Evidence Identifier Number which is listed at the top of the Screen

Evidence Identifier: DV-2008-MC-55928-3
Version No:1

Take note of this number for your reference.

Selecting OTG/IVD as Certification Details

If, at the Certification Issued Under drop down list you selected the option of IVD/OTG Quality System Certification, the options on this page change

IVD/OTG Quality System Certification

- Please Select --
- Council Directive 90/385/EEC (AIMD)
- Council Directive 93/42/EEC (MDD)
- IVD/OTG Quality System Certification**
- MRA Compliance Certification
- System or Procedure Pack DOC
- TGA Certification

You will be required to fill out the Manufacturers (as above)

And

Type in the Source of Certification in the free text field provided.

Click on

This will take you to Page 2 of Manufacturers Evidence.

Manufacturer Evidence - Page 2

TGA eBS Manufacturer Evidence

Evidence Identifier: DV-2008-MC-56140-3
Version No: 1

Page 2 - Enter the Scope of the Certification as GMDN Codes.

★ **GMDN Code** GMDN Codes can be added by using the Individual code selection based on a search of the GMDN list

Search for a GMDN Code:

Restrictions on Scope:

Enter the Scope of the Certification as GMDN Codes

At the GMDN (Global Medical Device Nomenclature) Code field you will need to initiate a search to find the relevant GMDN Code(s)

Click on the button.

The following screen appears

Search:

GMDN Text: (Minimum 3 characters to search for text)
 *Keywords including AND, AND NOT and OR may be used to refine your search

GMDN Code:

Search and Select the GMDN codes to add

Enter a search

List of GMDN code(s) associated with this application.
 Select OK to commit these changes.

Use the buttons below to remove entries from the list on the right

In the **GMDN Text:** field, type in the name or the starting letters of the device
 OR

In the **GMDN Code:** field, type in the code

Search:

GMDN Text: (Minimum 3 characters to search for text)
 *Keywords including AND, AND NOT and OR may be used to refine your search

GMDN Code:

Search and Select the GMDN codes to add

Enter a search

Press

(By typing in a minimum of the first 3 or 4 letters of the device, the system will list all GMDNs with those letters in the GMDN term.)



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The system produces a Selection of GMDN (Global Medical Device Nomenclature) containing your particular selection.
(In this instance – cotton)

Search: GMDN Text: Go (Minimum 3 characters to search for text)
*Keywords including AND, AND NOT and OR may be used to refine your search

GMDN Code:

Search and Select the GMDN codes to add

Cotton ball[11028]
Cotton roll, general-purpose[13414]
Cotton roll, general-purpose[31815]
Pad, cottonoid[32572]
Suture, cotton[13900]
Synonym-Cotton, ball dressing[38498]
Synonym-Cotton, roll[39188]
Synonym-Cottonoid pad[37433]
Synonym-Paddle, cottonoid[37718]
Synonym-Swab, cotton[15066]

To select the specific GMDN device, point and click on the GMDN to highlight your selection. From this point, you can view the definition of the highlighted selection.

You can make multiple selections of GMDN's by holding down the Control Key on your keyboard.

Click on

GMDN Definition : Cotton ball[11028]

A spherical mass of cotton or man-made fibres used as a swab to apply medications to or remove liquid from various parts of the body.

Primary Code and Term
11028 - Cotton ball

[Close Window](#)

A window screen similar to the above will appear, giving the definition for the highlighted GMDN.

To close the window.

Click on [Close Window](#)

If the highlighted GMDN is correct,

Click on

This adds your selection to the list of selected GMDN codes.
(you can select more than one GMDN – just repeat the selection process.)

Search and Select the GMDN codes to add

Cotton ball[11028]
 Cotton roll, general-purpose[13414]
 Cotton roll, general-purpose[31815]
 Pad, cottonoid[32572]
 Suture, cotton[13900]
 Synonym-Cotton gauze dressing[38496]
 Synonym-Cotton, roll[39188]
 Synonym-Cottonoid pad[37433]
 Synonym-Padgie, cottonoid[37718]
 Synonym-Swab, cotton[15066]

View Definition **Select**

List of GMDN code(s) associated with this application.
 Select OK to commit these changes.

Use the buttons below to remove entries from the list on the right.

Remove **Remove All**

Cotton ball[11028]
 Cotton roll, general-purpose[13414]
 Dressing, roll gauze[35017]

If you make a mistake, or wish to remove a selection, point to and highlight the item to be removed from the list, then

Click on **Remove**

If you wish to remove all of the items selected, simply

Click on **Remove All**

To cease making a GMDN Selection

To cease making a GMDN selection,

Click on **Cancel**

This will return you to Manufacturers Evidence screen where you can commence your search again.

Once you have finalised your selection of GMDN items,

Click on **OK**

This will automatically move your selection back to page 2 of the Manufacturers Evidence screen.

Entering Restrictions on Scope

If there is a Restriction on the Scope of your certification, enter the details in the **Restrictions on Scope field**, which is a free text field – simply type in the required text.

Restrictions on scope: **For example: Certification only covers Class IIa**

Click on **Next**

This takes you to page 3 of Manufacturers Evidence.



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Manufacturer Evidence - Page 3

TGA eBS Manufacturer Evidence

Previous Close Save View Entire App Validate Help

Evidence Identifier: DV-2008-MC-56140-3
Version No:1

Page 3 - Create Supporting Document list : [? What Type of Evidence?](#)

An electronic copy of your evidence MUST support this notification. You may, however, separately forward other hard copy documentation to the TGA supporting your notification.

Electronic Supporting Attachment List (Please limit file size to less than 1 mb. Contact Devices Help Desk if this is not possible).

[Add](#) No Attachments

Time Taken (optional)
Please enter the amount of time you spent (in minutes) completing this application. This includes reading time as well as time performing calculations and obtaining information.

Time taken minutes.

Create Supporting Document List - Evidence Types

You are required to provide a copy of the supporting documentation / evidence for your device. [? What Type of Evidence?](#) provides an explanation of the type of evidence required.

In Electronic Format

(Instructions on attaching an electronic copy of the supporting documentation/Evidence, (eg PDF, Word etc) to your Manufacturer Evidence.

Click on [Add](#)

Page 3 - Create Supporting Document list : [? What Type of Evidence?](#)

An electronic copy of your evidence MUST support this notification. However you may also provide other hard copy documentation to the TGA supporting your notification.

Electronic Supporting Attachment List (Please limit file size to less than 1 mb. Contact Devices Help Desk if this is not possible).

[Add](#) 

This takes you to a File Upload screen where you must specify:

- the Type of Conformity Document relating to your Manufacturer Evidence;
- And
- allows you to select the actual document from your own computer system.

File Upload

Application/Certificate Id: DV-2008-MC-56140-3
 Document Type: -- Please Select --
 Click Button to Select File:

Add

Please complete:

- The Document Type
- Select the File to be submitted.

Select a relevant Conformity **Document Type**: from the drop down list.

Application/Certificate Id: DV-2008-MC-55928-3
 Document Type: -- Please Select --
 Click Button to Select File:

Please complete:

- The Document Type
- Select the File to be submitted

Declaration of Conformity
 Design Examination Certificate
 Type Examination Report
 EC Certificate
 Updated EC Certificate
 MRA Certificate
 Additional supporting documentation
 Addition of GMDN code(s)
 Addition of Class(es)
 Preocedure pack declaration
 OTG - IVD Evidence
 TGA Conformity Assessment Certificate

Now use the **Browse...** button to select the relevant document on your Desktop/Computer. When you identify the correct document, click on the document

File Upload

Application/Certificate Id: DV-2008-MC-55928-3
 Document Type: Declaration of Conformity
 Click Button to Select File:

Click on **Add**

The Type of Document and Selected Document will be added to Page 3 of the Manufacturers Evidence screen.

Add

★ Declaration of Conformity - FL80707.xls **Remove**

Repeat this process to add any successive documents.

If you make a mistake or need to make a different selection,
 Click on **Remove**
 This will remove the attachment and you can commence your search again.

You have the option of providing information on the time it has taken to complete the Manufacturers Evidence form. This should be entered in whole numbers.



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You have now entered all the required information relating to Manufacturers Evidence.

Validating Manufacturer Evidence

Before you validate the details entered, you may wish to review the information entered into your Notification.

Click on

View Entire App

All the information you have entered will be set up in an easy to read, one page format. You may wish to print this for your (file) reference.

To return to the last page of the Manufacturers Evidence

Click on

Edit

Once you are satisfied with the information you have entered finalise the process,

Click on

Validate

Successful completion of the Manufacturers Evidence form will return

Validation Successful at the top of the screen as well as a Unique Evidence Identifier number.

NOTE:

If you miss an entry, the system will not Validate. The system will provide you with a message relating to any missing information - Eg

You have not attached any documents

You will need to go back and complete or correct the information before you can proceed. You can return to the relevant page by either clicking on the missed validation message or clicking on the previous button.

You should record this number for later reference.



Once your evidence has successfully validated, you will need to submit the application.

Click on

Submit

This completes Manufacturers Evidence.

You will find your Notification (Evidence Identifier) under the e-Business list heading “View Lodged Submissions”.

ACCEPTED MEDICAL DEVICE EVIDENCE AND CREATING A VARIATION

You may wish to use this option to review an accepted manufacturers evidence – to confirm the details. The option also enables you to Create a Variation of an Accepted Manufacturers Evidence. Such variations might include:

- adding another GMDN term;
- adding another Class;
- amending Manufacturers details; or
- updating certificate details (ie expiry date)

NOTE:

(Click on the  for an explanation of the current screen or field)
(Click on the  for an explanation of a question)

A variation to an accepted Manufacturer Evidence keeps the original [Application Identifier](#) - the version number will be updated.

Once accepted by the Therapeutic Goods Administration (confirmed by e-mail), your Manufacturers Evidence will appear within Accepted Manufacturers Evidence about 24 hours later and can be used with device applications.

From this point, you can identify Accepted Manufacturers Evidence and Create a Variation to an Existing Accepted Manufacturers Evidence.

Variations must meet specific requirements. Please ensure you are able to make a variation and are not required to submit a new Manufacturer Evidence form.

To commence Creating a Variation to Accepted Medical Device Evidence

Select [Accepted Medical Device Evidence](#) from the Main Menu

TGA eBusiness

- ▶ Portal - Therapeutic Goods Administration
- ▶ Sponsor cancellation
- ▶ TGA Information
- Label Checklist
- Accepted Medical Device Evidence 
- ▶ Accepted Manufacturer Information
- COMET
- SOLTRADE
- WAND
- Online Invoice Payment
- ▶ News
- ▶ Help
- ▶ Training
- Logout

Once you select Accepted Medical Device Evidence, the following screen appears.

TGA eBS Manufacturer Evidence - Accepted

Identifier	Sponsor Name	User Evidence Name	Manufacturer	Availability	Expiry Date	NB#
DV-2008-MC-56684-3	TGA Demo A	Manufacturer Evidence (Demonstration for All Classes)	Cipan (Portugal)[22619]	Released	20/08/2013	805
DV-2008-MC-56685-3	TGA Demo A	Manufacturer Evidence (Demonstration IVD OTG)	7 Med Industrie (France)[50033]	Released		

Locating Accepted Manufacturer Evidence

Scroll through the list to locate your Evidence Identifier code.

Use the  button
To bring up the next page.
OR

Click on 
Which brings up the following screen.

TGA eBS Search Manufacturer Evidence

[Home](#) [Refresh](#)

Enter Keyword(s): [Search](#)

Limit number of results to: [No limit](#)

Sort results by: [Relevance](#)

Exact Match Use Thesaurus

Type in any keywords from your application (eg cotton) and

Click on [Search](#)

This takes you back to the list of Manufacturers Evidence page where the section should have been greatly reduced – allowing you to make a quicker selection.

The Limit the number of results to: is a drop down list allowing you to restrict the number of results for your search from 10 to 200 items.

Limit number of results to: [No limit](#)

Sort results by: [Relevance](#)

Exact Match Use Thesaurus

The Sort results by: allows you to sort the results by the oldest date or newest date.

Sort results by: [Relevance](#)

Exact Match

You are also able to use the  sort option available on each heading to sort the evidence into alpha, numeric or date order.

[Identifier](#) [Sponsor Name](#) [User Evidence Name](#) [Manufacturer](#)

Selecting your Accepted Manufacturer Evidence

Once you have found the correct item, Point to and Click on the relevant Identifier code.

This will display the accepted Manufacturer Evidence you have selected.

TGA eBS Manufacturer Evidence

[Close](#) [Print](#) [Create Variation](#)

New Notification
Notification Details

Evidence Identifier:	DV-2008-MC-56684-3
Version No.:	1
Sponsor's Own Reference:	Manufacturer Evidence (Demonstration for All Classes)

Sponsor Details

Agent Name:	TGA Demo A
Sponsor Name:	TGA Demo A
Contact Details:	Device Demo - 02 6666 3333 - Devicedemo@tga.com.au

Certification Details

Certification Issued Under Directive:	TGA Certification
Manufacturer Name:	Cipan (Portugal)[22619]
Manufacturer Address as on Evidence:	Vala do Carregado Alenquer Lisbon 2580 Portugal S [57590]
Class of Device(s):	ALMD Class 1 Measurement Class 1 Sterile Class IIa Class IIb Class III
Conformity Assessment Procedure:	Schedule 3 Part 1 (Annex II)
Assessment Body:	Therapeutic Goods Administration [0805]

You should print a copy of this screen for your reference.

Click on [Print](#)

And follow the prompts to print the information.

Once you have confirmed that this is the correct Accepted Manufacturer Evidence, you can Create a (New) Variation.

Creating a Variation

Click on [Create Variation](#)

TGA eBS Manufacturer Evidence

[Close](#) [Print](#) [Create Variation](#) 

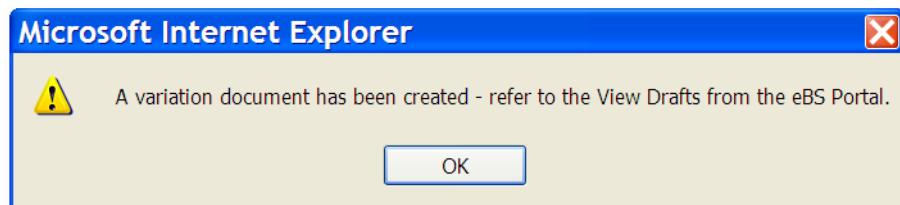
New Notification
Notification Details

The below information message will be displayed.

Click on OK.

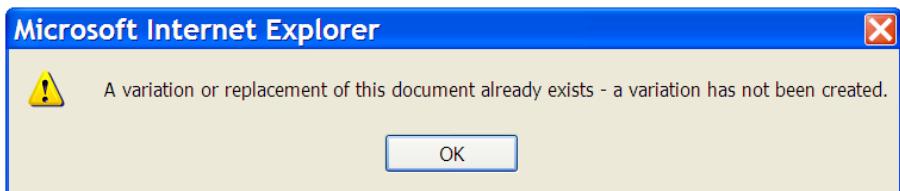


When the variation has been created you will be shown the below message.



This means that an identical document has been drafted and you can now access and amend that document under the View Drafts menu option.

NOTE: You can only undertake one Variation at any time. If a variation already exists, you will get the following message:



Click on 

This takes you back to the Manufacturer Evidence – Accepted page.

Click on 

This will return you to the Home Page where you can then

Select [Portal – Therapeutic Goods Administration](#)

When the screen drops down

Click on [View Drafts](#).

From this point you can identify and select your Variation document and make any necessary changes.

 Go to page 112 of View Drafts for search options.

Updating Manufacturers Evidence (Variation)

When you have identified your ‘cloned’ variation, point to and click on it.

Drafts					
Approval Area:		All Approval Areas			
Sponsor:		All Sponsors			
Search on:		Date for <input type="text"/> <input type="button" value="Reset All"/>			
Date	Identifier	Client Reference	Information	Sponsor	
2008-09-15	DV-2008-MC-56875-3	: Enter your own reference here		TGA Demo Spo	
2008-09-15	DV-2008-MC-56885-3	: Manufacturer Evidence (Demonstration IV/OTG)	7 Med Industrie (France)[50033]	TGA Demo A	
2008-09-11	DV-2008-MC-56825-3	: Demo	Harmed Medical (Harwill Medical) (South Africa)[27919]	TGA Demo A	
2008-09-11	DV-2008-MC-56884-3	: Manufacturer Evidence (Demonstration for All Classes)	Cipan (Portugal)[22819]	TGA Demo A	
2008-09-11	DV-2008-DA-56802-3	Cloning of ARTG number 153326	7 Med Industrie (France)[50033]	TGA Demo A	
2008-09-11	DV-2008-DA-56827-3	test	Mustang Industrial Corporation (Taiwan, Republic of China)[22283]	TGA Demo A	
2008-09-11	DV-2008-DA-56836-3	Test		TGA Demo A	

This will bring up the Manufacturers Evidence (Variation Screen)

TGA eBS Manufacturer Evidence (Variation)

You have not attached any new electronic documents

Variation to Evidence ID: DV-2008-MC-56684-3

Notification Details

Evidence identifier:	DV-2008-MC-56684-3
Version number:	2
Sponsor's own reference:	Manufacturer Evidence (Demonstration for All Classes)

You are now able to make a variation of the cloned evidence.

Note that the system gives a Version No: 2 to the Variation!

At Sponsor's Own Reference:

You can Change or Add additional information to enable you to more easily identify your (cloned) Manufacturer's Evidence (Variation).

The Certification details, Manufacturer Name and Address fields have been automatically populated. Under special conditions, if the Manufacturers name or address has changed, you can update the details.

To Change the manufacturers name and or address,

Click on

Which brings up the following additional fields

New Manufacturer Name:	<input type="text"/>
New Manufacturer Address:	<input type="text"/>
New Manufacturer Country:	<input type="text"/>

Type in the new name and or address.

You can add additional Classes to your application by clicking on the relevant box(s) at [Additional Classes\(s\) of Device](#):

You can choose an alternative
Conformity Assessment Procedure: (only if the conformity assessment procedures undertaken has increased in scope) and
Assessment body
by selecting from the drop down list.

You will need to type in the **Issuer's File Reference Number:**
And
Issuer Certificate Number:

Conformity Assessment Procedure:	Schedule 3 Part 3 (Annex IV) <input type="button" value="▼"/>
Assessment Body:	Therapeutic Goods Administration [0805] <input type="button" value="▼"/>
Issuer's File Reference Number:	<input type="text"/>
Issuer Certificate Number:	<input type="text"/>

You are also able to amend

[Evidence Re-Issue Date](#)
And
[Evidence Expiry Date](#)

Additional GMDN Codes

Your accepted evidence will have a list of GMDN Codes. You can add to these codes.

Click on

 Edit

The following screen will appear

The GMDN is a nomenclature system for medical devices for the purpose of exchange of regulatory data. The coding follows strict rules where the term is made up of a base concept (noun or phrase) followed by one or more qualifiers. For searching purpose, the system also employs synonyms.

Search: GMDN Text: (Minimum 3 characters to search for text)
*Keywords including AND, AND NOT and OR may be used to refine your search

GMDN Code:

In the **GMDN Text:** field, type in the name or the starting letters of the device
OR
In the **GMDN Code:** field, type in the code

Type in at least the first three characters of the device name.

Search: (Minimum 3 characters to search for text)

Text: *Keywords including AND, AND NOT and OR may be used to refine your search

GMDN Code:

Search and Select the GMDN codes to add

Protection equipment, laser beam, blocking wrap[17715]
 Sterilizer, microwave, unwrapped goods[37494]
 Sterilizer, microwave, wrapped goods[37495]
 Sterilizer, moist heat, unwrapped goods[40547]
Sterilizer, moist heat, wrapped goods[38671]
 Synonym-Pack, sterilization wrapper, bag and accessory[33471]
 Synonym-Wrap, burn[17604]
 Synonym-Wrap, implant, orbital[37295]
 Synonym-Wrap, sterilization[32221]
 Synonym-Wrap, tracheal tube, laser-resistant[42547]

Click on

By typing in a minimum of the first 3 letters of the device, the system will list all GMDNs with those letters in the device.

You can make multiple selections of GMDN's by holding down the Control Key on your keyboard.

The system produces a Selection of GMDN (Global Medical Device Nomenclature) containing your particular selection. (*In this instance – wrap*)

Point to and click on the required GMDN then

Click on

This takes you selection and puts it into a GMDN list box. You can continue to make further GMDN code selections by following this same sequence.

If you select the incorrect line/item you can remove one or more selection. To remove one selection, point to the item and then

Click on

To remove all selected items

Click on

When you have found all the GMDN codes, that you require, scroll to the bottom of the screen and

Click on

When searching for your GMDN item, if you need to view a definition of that item, highlight your selection then

Click on

This brings up the definition of your selected item.



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GMDNS Definition : Sterilizer, moist heat, wrapped goods[38671]

An apparatus for sterilizing packaged medical devices, e.g. surgical instruments, using steam as the sterilizing agent for the inactivation of micro-organisms.

Primary Code and Term
38671 - Sterilizer, moist heat, wrapped goods

[Close Window](#)

To close the definition screen

Click on [Close Window](#)

This takes you back to your search window

At Restrictions on Scope:

You should type in any restrictions on the scope of the manufacturer evidence.

Adding Supporting Documentation

You will need to attach an electronic copy of your supporting documentation. To do this

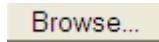
Click on [Add](#)

This takes you to a File Upload screen where you must:

- specify the Type of Document you have relating to your application; and
- select the actual document to be attached from your computer system.

Select a relevant **Document Type**: from the drop down list

Now use the

 **Browse...** button

to search for and select the relevant document(s) on your Desktop/Computer. Once you locate the relevant document,

Click on  **Add**

This attaches a copy of the document to your Variation of Device Application.

Add To Existing Electronic Supporting Attachment List	
 Add	
EC Certificate - Page 1.doc	
Design Examination Certificate - FL80707.xls	 Remove

NOTE: If the document has not changed, attach the same document again.

Once you have entered all the information required you can Validate your Variation to Accepted Medical Device Evidence.



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Validating your Variation to Accepted Medical Device Evidence

Click on

View Entire App

This combines all the information for your Variation to Accepted Manufacturer Evidence into a neat, easy to read format. You should print a copy of this page for your own reference.

Click on

Print

And follow the prompts to print a copy of the document.

Click on

Edit

This returns you to the Manufacturers Evidence (Variation) screen.

Click on

Validate

If all the information has been correctly added **Validation Successful** will appear at the top of the screen.

NOTE: If you miss an entry, the System will not Validate. The system will provide you with a message relating to any missing information - Eg
You have not attached any documents

You will need to go back and complete or correct the information before you can proceed. You can return to the relevant page by either clicking on the missed validation message or clicking on the previous button.

Click on

Submit

Which will submit your Manufacturer Evidence (Variation).

You should now find your submitted Manufacturer Evidence (Variation) under [View Lodged Submissions](#).



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DEVICE CHANGE REQUEST

Overview

A device change request form is used when an ARTG record needs to be changed. Circumstances where such a change may be necessary include, but are not restricted to:

- An expansion or contraction of the intended purpose of an included medical device;
- Amending the GMDN code to reflect a term which more accurately describes the kind of medical device covered by the ARTG entry;
- Correcting incorrect information supplied at the time of application;
- Notification of variations to product information in relation to Registered or Listed Therapeutic Goods.

NOTE:

(Click on the for an explanation of the current screen or field)
(Click on the for an explanation of a question)

An [Application Identifier](#) will be generated automatically when you save, close, validate, or go to the next page of the form).

A number of the fields will generate automatic information. This is based on your Log-In details. (Ie – Sponsor Details, address etc)

[Agent Details](#) will only be displayed if you have an Agent Log-In.

To Commence a Device Change Request

Select [Portal – Therapeutic Goods Administration](#)

When the screen drops down

Select [Create Applications and submissions](#)

Select [Medical Device](#)

then

Click on [Request Change](#) to open the link to

Entering Device Change Request Details

TGA eBS Device Change Request

Application Identifier: Will be generated on Validate

Sponsor Details

Agent name: TGA Demo A
 Sponsor name: TGA Demo A
 Contact name: Device Demo
 Email address: Devicedemo@tga.com.au
 Phone number: 02 6666 3333

Change Request

ARTG number:
 Change type:

 Variation to ARTG Listed Entry
 Variation to ARTG Registered Entry (High Level)
 Variation to ARTG Registered Entry (IVDs and Disinfectants)
 Variation to ARTG Included Entry

Description:

Sponsor Details

At the **Sponsor Name**: field select the relevant sponsor name from the drop down list (if applicable)

Agent Name:

Contact Name:

Email Address:

Phone Number:

will be automatically inserted and will depend your log-in.

Change Request Type

Type in your Australian Register of Therapeutic Goods Number at the **ARTG No** field.

Change Type:

You will need to select the type of change you are making by clicking the appropriate radio button

Change Request

ARTG number:
 Change type:

 Variation to ARTG Listed Entry
 Variation to ARTG Registered Entry (High Level)
 Variation to ARTG Registered Entry (IVDs and Disinfectants)
 Variation to ARTG Included Entry

Description:

Your selection will generate a fee amount payable at

Payment Details

Fee:

Type a brief **Description:** of the type of change you are making to your device.

Validating a Change Request

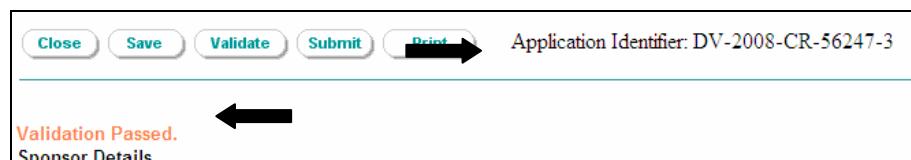
When you have entered your description

Click on 

The system will confirm if your Device Change Request has Passed Validation (ie Validation Passed).

The system will advise you if you have missed any fields.

It will also generate an Application Identifier number. The Application Identifier number will be listed at the top of the screen.



You should take note of this number for your reference.

Before you submit your Device Change, you will need to print off a copy for your records.

Click on 

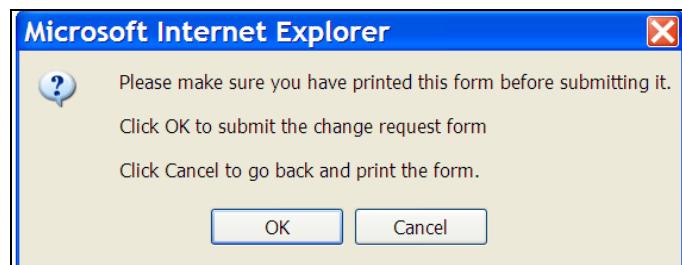
And follow the prompts to print a copy of the Change Request.

Keep this copy with your documentation relating to the Change Request.

To Submit your Change Request

Click on 

The system will warn you to print the form or press OK to submit.





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Printing a Tax Invoice

This produces a copy of your Tax Invoice from the TGA.

Note:

Please ensure you print this invoice. The invoice cannot be retrieved if you decide to submit your application without printing. If you do forget to print the invoice you will need to contact the Finance area of TGA on 1800 141 144 to obtain a copy.

 **Australian Government**
Department of Health and Ageing
Therapeutic Goods Administration

ABN: 40 939 406 804

Print Invoice and Submit application before closing the browser window.
[Return to Application](#) [Print](#) [Submit](#)

TGA Demo A

Tax Invoice		ONL014571
Date of Issue	16/09/2008	
Invoice Total	\$340.00	

Customer No.	Enquiries	Phone	Fax	Contact Email Address
51122	TGA Revenue Department	(02) 6232 8228	(02) 6232 8222	TGA.Account@health.gov.au

Identifier	Description	Unit Price	GST	Total
DV-2008-CR-56893-3	Variation to ARTG Listed Entry	\$340.00	0.00	\$340.00

Application fees are exempt from GST under Division 81 of A New Tax System (Goods & Services Tax) Act 1999

Subtotal	\$340.00
GST	\$0.00
Total	\$340.00

PAYMENT OPTIONS

ON-LINE PAYMENT OPTION

Credit card and Direct Debits may be paid on-line at:
<https://pnpnet.qvalent.com/tga>

When paying on-line the Reference Number printed below must be quoted.

Payment Reference No. L0145714

CREDIT CARD

CC Authorisation form is available at:
<http://www.tga.gov.au/docs/html/feesach.htm>

CHEQUES: Please make cheques payable to:
Therapeutic Goods Administration

and forward with a copy of this Invoice to:
PO Box 100
Woden ACT 2606

This invoice must be paid in full within 14 days to have your application processed. If you do not pay within this period your application will be withdrawn.

Please quote your Customer Number and Invoice Number in any correspondence
Customer Number: 51122 Invoice Number: ONL014571

A Receipt will only be issued on request

Click on

[Print](#)

To print a copy of the Tax Invoice.

If you make a mistake or need to make a change,

Click on

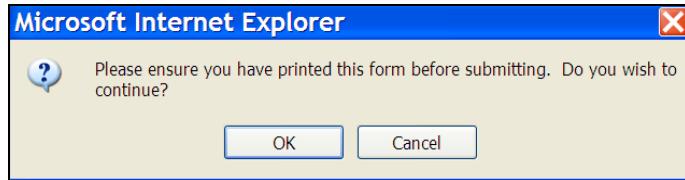
[Return to Application](#)

This will return you to Device Change Request validated screen where you can make any necessary amendments.

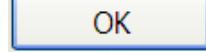
Once you are happy with your details, and have printed the Tax Invoice,

Click on 

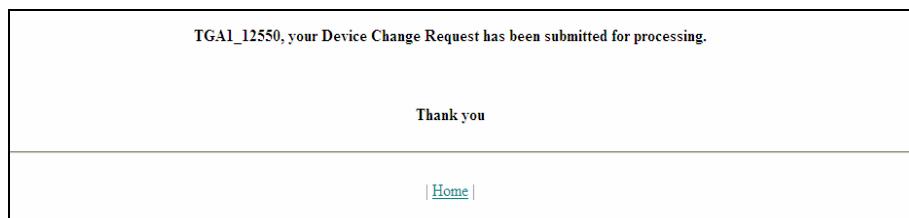
You will again be warned to print the Tax Invoice.



If you have printed the Tax Invoice,

Click on 

The system will submit your Device Change Request and provide you with a confirmation similar to the following.



This completes the Device Change Request form.

CONFORMITY ASSESSMENT

The TGA e-Business system allows you to make an application to the TGA for certification of a manufacturers Quality Management System. The details of the application must be in line with Parts 1 to 8 of Schedule 3 of the TGA Regulations.

Application for a Conformity Assessment Page 1

NOTE:

(Click on the  for an explanation of the current screen or field)
(Click on the  for an explanation of a question)

An [Application Identifier](#) will be generated automatically when you save, close, validate, or go to the next page of the form).

A number of the fields will generate automatic information. This is based on your Log-In details. (Ie – Sponsor Details, address etc)

[Agent Details](#) will only be displayed if you have an Agent Log-In.

To Commence a Conformity Assessment

Select [Portal – Therapeutic Goods Administration](#)

When the screen drops down

Select [Create Applications and submissions](#)

Select [Medical Device](#)

then

Click on [Conformity Assessment](#) to open the link to



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Application for a Conformity Assessment Certificate

TGA eBS Application for a Conformity Assessment Certificate

[Next](#) [Close](#) [Save](#) [View Entire App](#) [Validate](#) [Help](#)

Use this form if you are applying for:

- A TGA Conformity Assessment Certificate, under the Therapeutic Goods Act 1989, for a medical device and/or a medical device manufacturer.
- A TGA CE Certificate, according to the EU Medical Devices or Active Implantable Medical Device Directives and issued under the Australia - EU and/or Australia - EFTA Mutual Recognition Agreements, for Australian or New Zealand Manufacturers only.
- Changes to an existing conformity assessment certificate. If changes to existing CA certificates are required provide a detailed description in the Conformity Assessment Description field below.

Note:

- Read through the online help document for completing conformity assessment applications prior to making an application.
- This is the initial conformity (assessment) application form and no supporting electronic documentation is required at the time of lodgement. You will be required to submit a supplementary form along with documentation at a later date. Refer to the Conformity Assessment guidance document located on the TGA website at <http://www.tga.gov.au/docs/html/devguid3.htm>.

Application Identifier: Will be generated on save.
Version No:1

You will need to read and understand the text and related information on Conformity Assessment at the start of this screen. Understanding the requirements of and your obligations in relation to Conformity Assessment are essential to the successful lodging of an **Application for a Conformity Assessment Certificate**.

Once you are familiar with the information at the start of this screen, proceed to:

Applicant and Manufacturer Details

At Conformity Assessment Description:

- New applicants should type in your own reference;
- Existing holders of Conformity Assessment Certificates, type in the change required and the related Certificate number.

Applicant Details

At the Field Client Name:

your Client Name will be automatically selected (based on your Log-In);

Or

you will need to make a selection from the drop down Client Name list

★ Conformity assessment description:

Applicant Details

Agent name:	TGA Demo A
★ Client name:	<input type="text" value="TGA Demo A"/>
★ Contact name:	Device Demo
Contact email:	DeviceDemo@tga.com.au
★ Contact phone:	02 6666 3333
★ Contact fax:	02 9999 3333

The **Contact Name** and **Contact Email** will be automatically generated from your log-in. You may need to update your telephone and/or fax details.

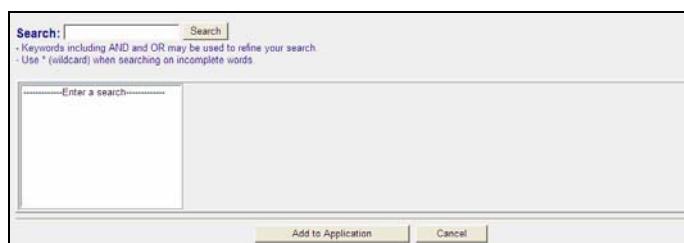
Existing Manufacturer Name

At the field **Manufacturer Name**:

You will need to search for the correct Manufacturer of your device.

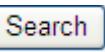
Click on the  button

The following search screen will appear



Search: Search
- Keywords including AND and OR may be used to refine your search.
- Use * (wildcard) when searching on incomplete words.
Enter a search
Add to Application Cancel

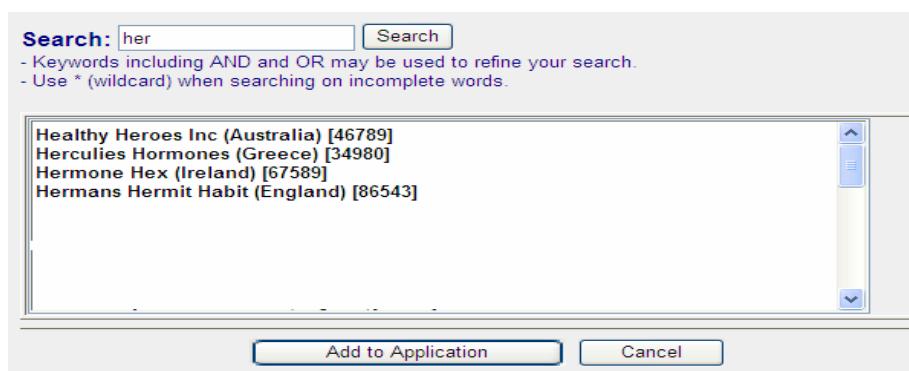
Search for your manufacturer by typing in the name or first few letters of the name then

Click on 



Search: Search
- Keywords including AND and OR may be used to refine your search.
- Use * (wildcard) when searching on incomplete words.

A list of recognised Manufacturers with the letters you have typed in the title, will be listed.

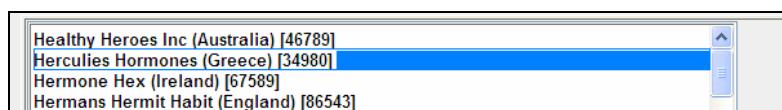


Search: Search
- Keywords including AND and OR may be used to refine your search.
- Use * (wildcard) when searching on incomplete words.

Healthy Heroes Inc (Australia) [46789]
Herculies Hormones (Greece) [34980]
Hermone Hex (Ireland) [67589]
Hermans Hermit Habit (England) [86543]

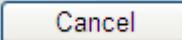
Add to Application Cancel

Select your Manufacturer by pointing to it and clicking.
This will highlight the Manufacturer.



Healthy Heroes Inc (Australia) [46789]
Herculies Hormones (Greece) [34980]
Hermone Hex (Ireland) [67589]
Hermans Hermit Habit (England) [86543]

If you click on the wrong selection and need to make a different selection,

Click on 

This will return you to the Application for a Conformity Assessment Certificate screen where you can commence your search again.



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Once you have selected your Manufacturer,

[Add to Application](#)

Click on

This will take your selection and insert it in the **Manufacturer Name** field on the Application for Conformity Assessment Certificate screen.

It will also automatically enter the Manufacturer Address in the **Manufacturer Address as on Evidence:** field.

Note:

There may be more than one address for this manufacturer – the address used should be the address that is supplied with any supporting evidence for the application.

If you make a mistake or need to make a different selection of manufacturer,

Click on [Remove](#)

This will clear the Manufacturers details in order for you to commence a new search.

New Manufacturer Name

At [New Manufacturer Name](#)

Type in the full name of the Manufacturer

At [New Manufacturer Address](#)

Type in the full address of the Manufacturer (eg street, Suburb, State)

At [New Manufacturer Country](#)

Select the Manufacturer's Country from the drop down list

New Manufacturer Name:

Creative Med Constructions

New Manufacturer Address:

124 Leggo Strassa, Vienna

New Manufacturer Country:

Austria

Completing Manufacture details

Once you have completed entering the Manufacture Name/Details (existing or new)

Click on [Next](#)

This will take you to Page 2 of the Conformity Assessment process.



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Application for a Conformity Assessment - Page 2

An [Application Identifier](#) will be generated automatically when you save, close, validate, or go to the next page of the form).

You should take a note of the Application Identifier Number for your later reference.

Certificate Device Details

Read the information relating to describing device details to get an idea of what is required regarding Device Details.

Previous Next Close Save View Entire App Validate

Application Identifier: DV-2008-CA-56213-3
Version No:1

Page 2 - Device Details

When describing Class Ia, Class Im, Class IIa and/or Class IIb devices which are the subject of this application, the description used does not need to include numbers, catalogue numbers, etc, but should describe a group of products that have the same intended use – eg. Urinary catheters, sterile surgical gloves, pulse oximeters, etc – product category. A Class III and AIMD product must include the Unique Product Identifier (UPI).

Device Details List

Unique Product Identifier (UPI) or 'Device Category' Description:	<input type="text"/>			
GMDN Code List: (if known)	<input type="text"/>			
<input type="button" value="Search"/>	(Only preferred terms, not <specify>)			
Classification	<input type="button" value="-- Please Select --"/>			
Classification Rule	<input type="text"/>			
Intended Use (250 max characters)	<input type="text"/>			
<input type="button" value="Add"/>	(Click to add Device details to list below)			
<input type="text"/> #	<input type="text"/> Device Description	<input type="text"/> GMDN Code	<input type="text"/> Classification	<input type="text"/> Classification Rule
<input type="text"/> Intended Use				
To Remove, Enter Item #: <input type="text"/> <input type="button" value="Remove"/>				

Device Details List

At the [Unique Product Identifier \(UPI\)](#) field type in your Unique Product Identifier or Description/Device Category.

At the [GMDN Code List](#): search for any GMDN (Global Medical Device Nomenclature) codes

Click on

The following screen will appear

The GMDN is a nomenclature system for medical devices for the purpose of exchange of regulatory data. The coding follows strict rules where the term is made up of a base concept (noun or phrase) followed by one or more qualifiers. For searching purpose, the system also employs synonyms.

Search: GMDN Text: (Minimum 3 characters to search for text)
*Keywords including AND, AND NOT and OR may be used to refine your search

GMDN Code:

Enter a search.....



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In the **GMDN Text:** field, type in the name or the starting letters of the device
OR

In the **GMDN Code:** field, type in the code

Type in at least the first three characters of the device name.

The GMDN is a nomenclature system for medical devices for the purpose of exchange of regulatory data. The coding follows strict rules where the term is made up of a base concept (noun or phrase) followed by one or more qualifiers. For searching purpose, the system also employs synonyms.

Search:GMDN Text: (n characters to search for text)
*Keywords including AND, AND NOT and OR may be used to refine your search

GMDN Code:

Burn wrap[36093]
Protection equipment, laser beam, blocking wrap[17715]
Sterilizer, microwave, unwrapped goods[37494]
Sterilizer, microwave, wrapped goods[37495]
Sterilizer, moist heat, unwrapped goods[40547]
Sterilizer, moist heat, wrapped goods[38671]
Synonym-Pack, sterilization wrapper, bag and accessory[33471]
Synonym-Wrap, burn[17604]
Synonym-Wrap, implant, orbital[37295]
Synonym-Wrap, sterilization[32221]
Synonym-Wrap, tracheal tube, laser-resistant[42547]

Click on

By typing in a minimum of the first 3 letters of the device, the system will list all GMDNs with those letters in the device.

The system produces a Selection of GMDN (Global Medical Device Nomenclature) products containing your particular selection. (*In this instance – wrap*)

When searching for your GMDN item, if you need to view a definition of that item, highlight your selection then

Click on

This brings up the definition of your selected item.

GMDNS Definition : Synonym-Pack, sterilization wrapper, bag and accessory[33471]

A device intended to enclose medical devices that are to be sterilized. It is designed to allow sterilization of the enclosed medical device and also to maintain sterility of the device until the packaging is opened for use of the device, or until a predetermined shelf date is expired.

Primary Code and Term
37395 - Sterilization packaging, <specify>

[Close Window](#)

To close the definition screen

Click on [Close Window](#)

This takes you back to your search window

If you select the incorrect line/item. Scroll to the bottom of the screen and

Click on

This will return you back to Page 2 of the Conformity Assessment screen where you can commence your search again.



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Once you have identified your selection, Point to and click on the correct item to highlight it.

Scroll to the bottom of the screen and

Click on

This takes your selection back to Page 2 of the Conformity Assessment.

Next - Select the Classification of the Device from the drop down list at **Classification:**

Classification
Classification Rule
Intended Use (250 max characters)
Add (Click to add)
You must enter the D
Device Description
GMDN Code
Classification
Classification Rule

At **Classification Rule:** type in the final classification rule from Schedule 2 of the TGA Medical Device Regulations

And type in a short description of the intended use of the device at **Intended Use:**

Click on

The Device Description, GMDN Code, Classification, Classification Rule and the description of Intended Use is listed on the screen and formatted as follows:

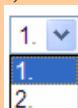
#	Device Description	GMDN Code	Classification	Classification Rule
1.	Sterile Protective Wrappers	Sterilization packaging. <specify>	Class 1 Sterile	Rule XXXX

Intended Use
1. To allow sterilisation of enclosed device

To Remove, Enter Item #:

Repeat the above sequence for each new device.

If you make a mistake or need to make an amendment, at Remove, Enter Item #, Click on the drop down list



Point to and click on the line number of the item that needs to be removed, Click on

This will clear the Device Description, GMDN Code, Classification, Classification Rule and Intended use fields. You can then re-build your device description starting at the [Unique Product Identifier \(UPI\)](#) or [Device Category Description](#) field.



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Selecting a Device Classification Level

Select the Highest Classification of a Device

that is to be covered by this application by clicking on the relevant box.

<input type="checkbox"/> AIMD
<input type="checkbox"/> Class 1 Measurement
<input checked="" type="checkbox"/> Class 1 Sterile
<input type="checkbox"/> Class IIa
<input type="checkbox"/> Class IIb
<input type="checkbox"/> Class III

Conformity Assessment Procedure

Select the relevant **Conformity Assessment Procedure** from the drop down list.

★ Select Conformity Assessment Procedure(s) Required

★ Is Certification in accordance with the EU Medical Implantable Medical Device Directive required?

Schedule 3, Part 2 only
--- Please Select ---
Schedule 3, Part 1, clause 1.6 only (design dossier review)
Schedule 3, Part 1, excluding clause 1.6 (design dossier review)
Schedule 3, Part 1, including clause 1.6 (design dossier review)
Schedule 3, Part 2 only
Schedule 3, Part 2 + Schedule 3, Part 3
Schedule 3, Part 2 + Schedule 3, Part 4
Schedule 3, Part 2 + Schedule 3, Part 5
Schedule 3, Part 3 only
Schedule 3, Part 4 only
Schedule 3, Part 5 only

EU Medical Device Requirements

You then need to confirm whether Certification in accordance with EU Medical Device or Active Implantable Medical Device Directives is required by selecting either the Yes or No radio button. Yes No

★ Is Certification in accordance with the EU Medical Device Directive or Active Implantable Medical Device Directive required? Yes No

Once you have made your selection

Click on **Next**

At the top or the bottom of the screen.

This will take you to Page 3 – Conformity Assessment.

Application for a Conformity Assessment – Page 3

TGA eBS Application for a Conformity Assessment Certificate

[Previous](#) [Close](#) [Save](#) [View Entire App](#) [Validate](#) [Continue](#) [Help](#)

Page 3 - Applicant's Certification

Application Identifier: DV-2008-CA-56894-3
Version No: 1

Application ID : DV-2008-CA-56894-3
 Manufacturer ID :
 Submission date : 16/09/2008
 Client name: TGA Demo A
 Applicant name: TGA Demo A
 Conformity assessment description : Enter your own reference here
 Manufacturer name : New Manufacturer
 New manufacturer name : New Manufacturer
 Manufacturer address :
 Device class : CLAS2B
 GMDNS code : Patient monitor, heart rate[35197]
 Conformity assessment procedure : Schedule 3, Part 1, excluding clause 1.6 (design dossier review)

Declaration

In electronically submitting this application to TGA, I hereby declare that in relation to this Conformity assessment application the information given in this application and the below statements on this declaration form are current and correct.

PLEASE NOTE: A false declaration will result in the application being considered ineffective and terminated.

I agree Yes No

Time Taken (optional)
Please enter the amount of time you spent (in minutes) completing this application. This includes reading time as well as time performing calculations and obtaining information.

Time taken: minutes

Applicant's Certifications

Page three lists details that you have entered in relation to the Conformity Assessment. If all the information is correct, you can now electronically submit this information.

If you are satisfied that all the information is correct and current, click on the Yes button. Note that a false declaration will result in the application being considered ineffective and will be terminated.

I agree Yes No

If you identify any incorrect information and wish to correct it

Click on [Previous](#)

And return to either screen 1 or 2 to correct the information.

You should view and print the details of the entire document before you validate the form (*this further ensures the details entered are correct*).

Validating Conformity Assessment

Click on [View Entire App](#)

Check the details on the screen. If they are all correct

Click on [Print](#)

And follow the prompts to print the form and keep it for your reference.

Click on [Edit](#)

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To return to page 3 of the Application for a Conformity Assessment Certificate form.

Once you are satisfied with the information you have entered ensure you have agreed to the information and finalise the process.

Click on

Validate

Successful completion of the Application for a Conformity Assessment Certificate form will return

Validation Successful

at the top of the screen.

NOTE:

If you miss an entry, the system will not Validate. The system will provide you with a message relating to any missing information - Eg

The highest classification of a device requires at least one entry to be selected.**You have not agreed to the declaration**

You will need to go back and complete or correct the information before you can proceed. You can return to the relevant page by either clicking on the missed validation message or clicking on the previous button.

Printing a Tax Invoice

You will now need to print your Tax Invoice and submit the application.

To do this

Click on

Continue

This produces a Tax Invoice.

Australian Government							
Department of Health and Ageing							
Therapeutic Goods Administration							
ABN: 40 939 406 804							
Print Invoice and Submit application before closing the browser window.							
Return to Application Print Submit							
TGA Demo A							
<table border="1"><tr><td>Tax Invoice</td><td>ONL014573</td></tr><tr><td>Date of Issue</td><td>16/09/2008</td></tr><tr><td>Invoice Total</td><td>\$740.00</td></tr></table>		Tax Invoice	ONL014573	Date of Issue	16/09/2008	Invoice Total	\$740.00
Tax Invoice	ONL014573						
Date of Issue	16/09/2008						
Invoice Total	\$740.00						
Customer No.	Enquiries	Phone	Fax	Contact Email Address			
51122	TGA Revenue Department	(02) 6232 8228	(02) 6232 8222	TGA.Account@health.gov.au			
Identifier	Description	Unit Price	GST	Total			
DV-2008-CA-56894-3	Conformity Assessment	\$740.00	0.00	\$740.00			
Application fees are exempt from GST under Division 81 of A New Tax System (Goods & Services Tax) Act 1999							
PAYMENT OPTIONS							
ON-LINE PAYMENT OPTION							
Credit card and Direct Debits may be paid on-line at: https://pnpnet.gvlnet.com/tga							
When paying on-line the Reference Number printed below must be quoted.							
Payment Reference No. L0145730							

Click on

Print

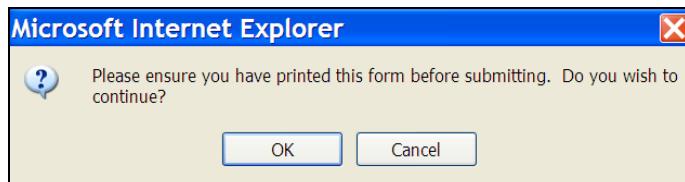
to print the Tax Invoice.

Once you have printed your Tax Invoice, you can submit the application.

To submit your application,

Click on **Submit**

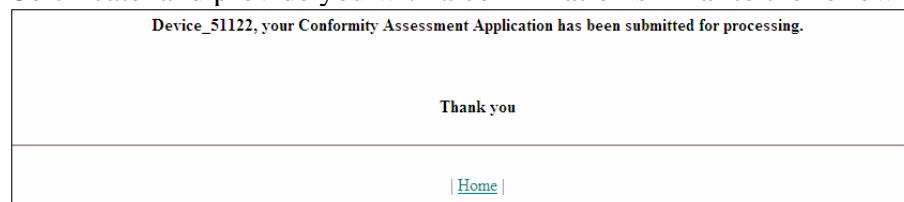
The following warning pops up



If you have printed your Tax Invoice,

Click on **OK**

The system will submit your Application for a Conformity Assessment Certificate and provide you with a confirmation similar to the following:



Click on | [Home](#) |

To return to the TGA e-Business Services Home Page.

You should now find your lodged Conformity Assessment under [View Lodged Submissions](#).



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CLASS III/AIMD VARIATION

The Class III/AIMD Variation section of the TGA e-Business system allows you to make changes to your Class III or AIMD ARTG entry. Changes relate to small details such as variants (ie length of a catheter). **Changes must not change the intended purpose of the device.**

Variation of Device Class III/AIMD ARTG Entry - Page 1

NOTE:

(Click on the for an explanation of the current screen or field)

(Click on the for an explanation of a question)

An [Application Identifier](#) will be generated automatically when you save, close, validate, or go to the next page of the form).

A number of the fields will generate automatic information. This is based on your Log-In details. (Ie – Sponsor Details, address etc)

[Agent Details](#) will only be displayed if you have an Agent Log-In.

To Commence Variation (Class III/AIMD)

If your variation relates to a Class III/AIMD ARTG entry then

Select [Portal – Therapeutic Goods Administration](#)

When the screen drops down

Select [Create Applications and Submissions](#)

Select [Medical Device](#)

then

Click on [Class III/AIMD Variation](#) to open the link to

TGA eBS Variation of Device Application

Next Close Save View Entire App Validate Help

Application Identifier: Will be generated on save

Page 1 Application Details

★ Application for: Medical Device - Included

★ Sponsor's own Reference:

Sponsor Details



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Variation of a Device - Application Details

Application for:

Is automatically generated.

At the Field

Sponsor's Own Reference:

enter your own reference details

You will need to come back and re-enter your Sponsor's Own Reference after you have 'Cloned' your ARTG entry Number. The system automatically over-rides your own Sponsor's Own Reference with wording similar to 'Variation of Licence 123456')

Application Details	Medical Device - Included
★ Application for:	Variation of Licence 146581
★ Sponsor's own Reference:	

Agent Name

Is automatically generated (based on your Log-In)

Sponsor Details

At the Field Sponsor Name:

your Sponsor Name will be automatically selected (if you are a sponsor);

Or

if you are an agent, you will need to make a selection from the drop down Sponsor Name list

Sponsor Details	
★ Agent name:	TGA Demo A
★ Sponsor name:	TGA Demo A
★ Contact name:	TGA Demo A
Contact email:	TGA Demo Spo Devicedemo@tga.com.au

The Contact Name and Contact Email will be automatically generated from your log-in.

This application is to: make a variation to an existing ARTG entry, the option is already identified

 Make a variation to an existing ARTG entry

Identifying/Searching Class III/AIMD ARTG Entries

At This application is to: you can choose to type in the ARTG entry number if you know it and then

Click on 

or

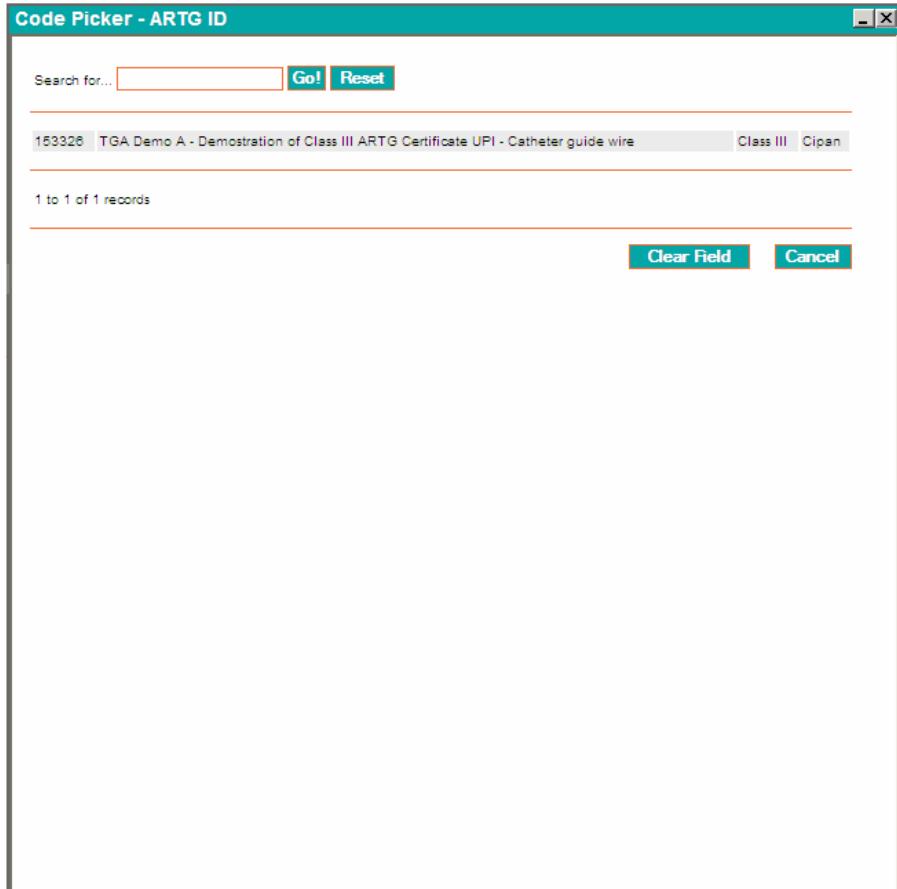
Click on 

This will bring up a Code Picker list of your ARTG Class III/AIMD entries.



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This pop up screen allows you to:

Narrow the field of search by entering the first few numbers of the ARTG number (if known) or a few characters in the name of the device or

manufacturer and pressing **Go!**

OR

Scroll through the entire list to find the specific device.

You can move through the pages of your ARTG Inclusions by using the following arrow keys.



Clicking on **Reset**

Will reset the search and re-list all the device items.

Once you have located your device, point to and click on the correct line.

This automatically takes your selected ARTG code number and inserts it into the **This application is to:** field on your application.

If you make a mistake or need to make a change,

Click on **Search**

This will return you to the Code Picker list where you can make an



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alternative selection.

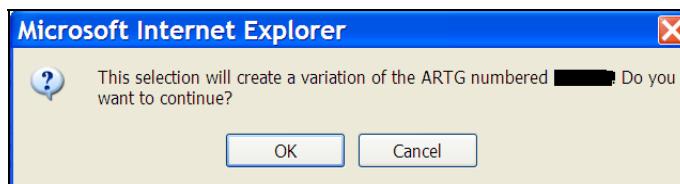
Once you are satisfied with your selection you can now clone the ARTG inclusion to allow you to vary the details.

NOTE: Making a clone, effectively initiates a new application by producing a replica/copy of the selected ARTG entry.

Cloning a Class III/AIMD ARTG Entry

Click on **Clone**

The following screen appears



If this is the correct ARTG number required,

Click on **OK**.

This returns the following (or similar) information at the Application Class Details field now found at the bottom of the screen.



If you have made a mistake or wish to select a different ARTG number

Click on **Cancel**

You can then select **Clone** again and search and select the correct ARTG number

Click on **Next**

To take you to the second page of Manufacturing Details (Other Classes).



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Variation of Device application (other Classes) - Page 2B

Page 2B - Manufacturing Details (Other Classes)

Application Identifier: DV-2008-DA-56802-3

Unique Product Identifier:
The UPI is the unique name that is assigned to the product
Cipan (Portugal)[22619]
Catheter guide wire[35094]

Demonstration of Class III ARTG Certificate UPI - Catheter guide wire
Note: This field is limited to 130 characters

Functional description:
The functional description should describe the operation of the medical device, not its composition.

Total number of devices covered: 12

Manufacturing Details (Other Classes)

A new Application Identifier number will be allocated to the Application. This number is found at the top right hand side of the screen.

Application Identifier: DV-2008-DA-56203-3

You can amend certain information relating to the Manufacturing Details for (other Class) Variation of Device Application.

Developing a List of Device Details

A medical device is taken to be of the same kind as another medical device if they have the same

Sponsor

Manufacturer,

GMDN,

Classification and

Are the same in relation to such other characteristics as the regulations prescribe (ie – intended purpose).

Thus some of the fields on this screen cannot be changed as it would constitute the requirement for a new ARTG entry. The fields that cannot be changed include:

Manufacturer

And

GMDN Code and Description:

You can add or delete the information in the following fields:

Unique Product Identifier

and

Functional Description:

Use the scroll bar/arrows to scroll through the information. Place your cursor where you wish to make edits, click and type in your information.

Remember, changes must not effect the intended purpose of the medical device.

Unique product identifier: The UPI is the unique name that is assigned to the product	Demonstration of Class III ARTG Certificate UPI - Catheter guide wire Note: This field is limited to 130 characters.
Functional description: The functional description should describe the operation of the medical device, not its composition.	This functional description and variants details below are only for demonstration purposes.
Total number of devices covered: 12	

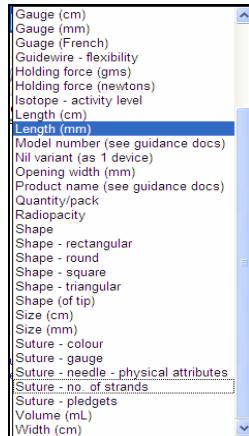
The **Total number of Devices Covered:** field is a free text field.
Adjust the number of Devices covered by typing in the number.

Click on  For information/guidance on the meaning of Variant to ensure you have an understanding of what an allowable Variant is.

Note: You cannot remove any existing variant, you can only add a variant.

At Variant Type

Click on the drop down list for a list of allowable variant types



Use the scroll bar to scroll through the selection. When you find your preferred variant, point and click on the selection.

Variant Range is a free text field

Type in your Variant Range

Once you are satisfied with your Variant Type and Variant Range

Click on 

Your selection will be added to the **Variant List:** at the bottom of the screen.

Variant type:	Diameter (mm)	
Variant range:		
Add		
#	Variant type	Variant range
1.	Diameter (mm)	2-4
2.	Length (cm)	20-50

Only Variations you have made on this application can be removed.
If you make a mistake or wish to remove the selection from your Variant List, At **To remove item number from list:**



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Select the line number of the item you wish to remove from the drop down list, then
Click on **Remove**.

Once you are satisfied with the information on this screen, including the Variant List

Click on **Next**

This will take you to Page 5 of Variation of Device Application.

Variation of Device Application (other Classes) - Page 5

Certification of Variation of Class III/AIMD Application

At the top of the page, you will find a number of your application details including:

TGA eBS Variation of Device

Previous Close Save View Entire App V

Page 5 - APPLICANT'S CERTIFICATION

Application ID :
Submission Date :
Sponsor Name:
Agent Name:
Sponsor own reference :

Device Class:
Unique Product Identifier:

Manufacturer Name:
New Manufacturer Name:
Manufacturer Address:
GMDN description:
Intended purpose:

Check that the details are correct before proceeding.

If you have made a mistake or the details are incorrect, you will need to go back to make any changes. To go back

Click on **Previous**

Attaching Conformity Documents to a Variation of Device Application

If you are satisfied that the details are correct you can now electronically attach your supporting documentation.

At **Function to attach/add supporting documentation**

Click on **Add**

This takes you to a File Upload screen where you must:

- specify the Type of Document you have relating to your application; and
- select the actual document to be attached from your computer system.

Note: You are required to attach new documentation. Existing attachments will remain in place and cannot be removed.

File Upload

Application/Certificate Id: DV-2008-DA-56079-3
 Document Type: -- Please Select --
 Click Button to Select File:

Please complete:

- The Document Type
- Select the File to be submitted

Done Internet

Select a relevant **Document Type**: from the drop down list

Document Type: -- Please Select --

Click Button to Select File:

Please complete:

- The Document Type
- Select the File to be submitted

-- Please Select --
 Declaration of Conformity
 Design Examination Certificate
 Type Examination Report
 EC Certificate
 Updated EC Certificate
 MRA Certificate
 Additional supporting documentation
 Addition of GMDN code(s)
 Addition of Class(es)
 Procedure pack declaration
 OTG - IVD Evidence
 TGA Conformity Assessment Certificate

Now use the

button

to search for and select the relevant document on your Desktop/Computer.
 Once you locate the relevant document,

Click on

This attaches a copy of the document to your Variation of Device Application.

★ No existing attachment

TGA Conformity Assessment Certificate - FL80707.xls

If you make a mistake or need to make a different selection,
 Click on

This will remove the document in the Variation of Device Application screen. You can then Click on to go back and search for and attach the correct document.

NOTE: Before you can finalise your application, you must read through the declaration in the scroll down screen.



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Validating a Variation of Device Application

Before you Validate your application, you should view and print your application.

Click on [View Entire App](#)

Check the details on the screen. If they are all OK

Click on [Print](#)

And follow the prompts to print the form and keep it for your reference.

You should also read the declaration on this page. Once you have read the information on this screen,

Click on [Edit](#)

This will return you to the Variation of a Device Application screen.

If you are satisfied that all the information is correct, you will need to agree to the declaration by clicking on the Yes button.

I agree	<input checked="" type="radio"/> Yes	<input type="radio"/> No
---------	--------------------------------------	--------------------------

You can now validate the application.

Click on [Validate](#)

Successful completion of the Variation of a Device Application form will return **Validation Successful** at the top of the screen.

The unique Application Identifier number will also be listed. You should record this number for later reference.

Validation Successful	Application Identifier: DV-2008-DA-56075-3
-----------------------	--

NOTE:

If you miss an entry or fail to click on the Yes in the declaration, the System will not Validate. The system will provide you with a message relating to any missing information - Eg

[You have not attached a supporting document](#)

[You have not agreed to the declaration](#)

You will need to go back and complete or correct the information before you can proceed. You can return to the relevant page by either clicking on the missed validation message or clicking on the previous button.

Printing a Tax Invoice

Once you have validated your Variation, you will need to print the system produced Tax Invoice. To do this



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Click on

Continue

The system will produce a Tax Invoice from the TGA.

Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

ABN: 40 939 406 804

Print Invoice and Submit application before closing the browser window.

[Return to Application](#) [Print](#) [Submit](#)

Tax Invoice	ONL014231
Date of Issue	19/06/2008
Invoice Total	\$330.00

Customer No.	Enquiries	Phone	Fax	Contact Email Address
23932	TGA Revenue Department	(02) 6232 8228	(02) 6232 8222	TGA.Account@health.gov.au

Identifier	Description	Unit Price	GST	Total
DV-2008-DA-56075-3	Medical Device - Included	\$330.00	0.00	\$330.00

Application fees are exempt from GST under Division 81 of A New Tax System (Goods & Services Tax) Act 1999

Subtotal	\$330.00
GST	\$0.00
Total	\$330.00

PAYMENT OPTIONS

ONLINE PAYMENT OPTION

Credit card and Direct Debit may be paid on line at:

Click on

Print

To print a copy of the Tax Invoice.

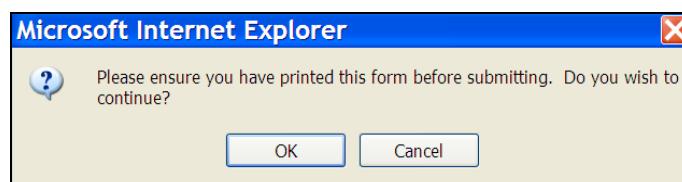
Note:

Please ensure you print this invoice. The invoice cannot be retrieved if you decide to submit your application without printing. If you do forget to print the invoice you will need to contact the Finance area of TGA on 1800 141 144 for a copy.

Once you are happy with your details, and have printed the Tax Invoice,

Click on **Submit**

You will again be warned to print the Tax Invoice.



If you have printed the Tax Invoice,

Click on

OK

The system will submit your Variation of a Device Application and provide you with a confirmation similar to the following.



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Device_51122, your Device Application DV-2008-DA-56899-3 has been submitted for processing.

Thank you

| [Home](#) |

You should now find your application for a Class III/AIMD Variation under [View Lodged Submissions](#).



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DEVICE APPLICATION

An Overview

The Device Application form is used to include a Medical Device or to have an Other Therapeutic Good listed/registered on the Australian Register of Therapeutic Goods (ARTG).

The form is made up of 12 pages of which you will only see a maximum of Five (5). Some pages have slight variations (ie Page 1 has 2 variations and Page 2A has 3 variations, 2B has 3 variations). The system will only display the pages relevant to the type of Application being submitted.

Device Application (Medical Device – Other Classes) – Page 1

Medical Device - Included
Medical Device - Included (Export Only)
Other Therapeutic Good - Registered disinfectant
Other Therapeutic Good - Registered IVD
Other Therapeutic Good - Registered other (i.e. human origin products)
Other Therapeutic Good - Listed disinfectant
Other Therapeutic Good - Listed IVD
Other Therapeutic Good - Listed other
Other Goods - not medical devices - Export Only

These notes relate to the above circled selections found in the drop down list at [Application For](#):

They are also relevant for :

Medical Device – Included

- Class 1 Measurement
- Class 1 Sterile
- Class IIa
- Class IIb
- Class III and
- AIMD

NOTE:

(Click on the  for an explanation of the current screen or field)
(Click on the  for an explanation of a question)

An [Application Identifier](#) will be generated automatically when you save, close, validate, or go to the next page of the form).

A number of the fields will generate automatic information. This is based on your Log-In details.

[Agent Details](#) will only be displayed if you have an Agent Log-In.

If you are applying for a Device Application – Included (Class 1), please go to the Separate Section documented specifically for Device Application – Included (Class 1).

To commence a Device Application (Other Classes)

Select [Portal – Therapeutic Goods Administration](#)

When the screen drops down

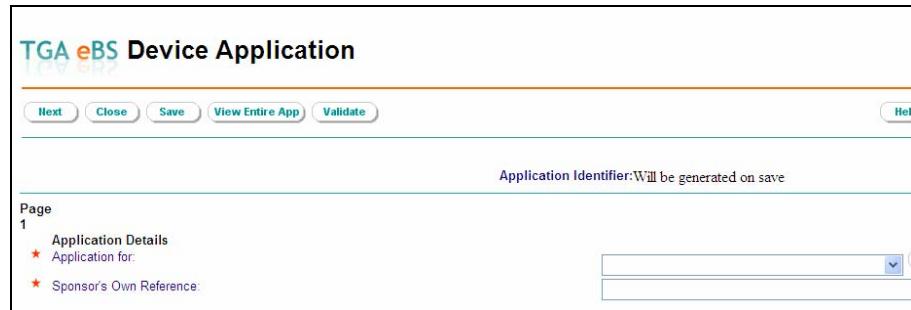
Select [Create Applications and submissions](#)

Select [Medical Device](#)

then

Click on [Device Application](#) to open the link to

This brings you to the first page of Device Application



Device Application Details

[Application For:](#)

Select your application type

From the drop down list.

Application Details ★ Application for: ★ Sponsor's own reference: Sponsor Details Agent name: ★ Sponsor name: ★ Contact name: Contact email:	 <div style="border: 1px solid black; padding: 5px; width: 250px; height: 100px; background-color: #f0f0f0;"> Medical Device - Included Medical Device - Included (Export Only) Other Therapeutic Good - Registered disinfectant Other Therapeutic Good - Registered IVD Other Therapeutic Good - Registered other (i.e. human origin products) Other Therapeutic Good - Listed disinfectant Other Therapeutic Good - Listed IVD Other Therapeutic Good - Listed other Other Goods - not medical devices - Export Only </div>
---	--

This will automatically initiate the creation of your Application Identifier: number at the top of the screen.

TGA eBS Device Application	
     	
 Application Identifier: DV-2008-DA-56309-3	

At the Field **Sponsor's Own Reference:** enter your own reference details.

Sponsor Details

Agent Name:

will be automatically selected (based on your log-In);

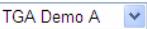
Sponsor Name:

will be automatically selected (based on your log-In);

Or

you will need to make a selection from the drop down **Sponsor Name:** list.

The **Contact Name** and **Contact Email** will be automatically inserted and will depend your log-in.

Sponsor Details Agent name: ★ Sponsor name: ★ Contact name: Contact email:	TGA Demo A  Device Demo Devicedemo@tga.com.au
---	--

Address Details

Address(es) are automatically generated, based on your (log-In)

You may have more than one address. If you have more than one address, ensure that your billing address and your Regulatory Address are stated separately in the correct field.

At **Billing Address:**

Select your correct address for billing/account purposes from the drop down list.

At **Regulatory Correspondence Address:**

Select your correct address for Compliance/Regulatory purposes from the drop down list.

Billing address:	PO Box WODEN ACT 2606
Regulatory correspondence address:	PO Box WODEN ACT 2606
	PO Box WODEN ACT 2606

The next step is already selected for you.

This application is to:	<input checked="" type="radio"/> Create a new register <small>The new application can be based</small>
-------------------------	---

Cloning an ARTG Inclusion For a Device Application

Note: If you already have a similar medical device included on the ARTG, you can 'Clone' or copy the details of that ARTG entry and change any relevant details. ARTG entries - Included Medical Device (Export only) and Other Therapeutic Goods (Registered, listed and Export only) can not be cloned. You can choose to leave this field empty and go to the next step – Manufacturer's intended purpose for the device:

At ARTG Number:

You can leave this box empty.

If you have an ARTG inclusion and know the [ARTG Number](#):

Type the code in the ARTG Number box Or

Click on [Search](#)

This will bring up a Code Picker list of your ARTG inclusions.

Code Picker - ARTG ID

Search for...		Go!	Reset
153429	TGA Demo A - Cardiac mapping system catheter, oesophageal, reprocessed	Class 1	Biotronik AG
153326	TGA Demo A - Demonstration of Class III ARTG Certificate UPI - Catheter guide wire	Class III	Cipan
153430	TGA Demo A - Depressor, tongue	Class 1	Boston Scientific Precision Vascular
153414	TGA Demo A - Drainage bag	Class 1	Medko Med

1 to 4 of 4 records

[Clear Field](#) [Cancel](#)

The Code Picker list allows you to:

Narrow the field of search by entering the first few numbers of the ARTG

number (if known) or a few characters in the name of the device or

manufacturer and pressing [Go!](#)

OR

Scroll through the entire list to find the ARTG entry.



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You can move through the pages of your ARTG Inclusions by using the following arrow keys.



Clicking on **Reset**

Will reset the search and re-list all the ARTG entries.

Once you have located your ARTG entry, point to and click on the correct line.

This immediately takes your selected ARTG code number and inserts it into the **ARTG Number** box on your application.

If you make a mistake or need to make a change,

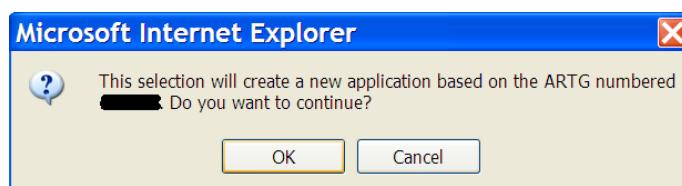
Click on **Search**

This will return you to the Code Picker list where you can make an alternative selection.

Once you have the ARTG number you wish to copy details of

Click on **Clone**

The following pop up, confirmation screen appears.



If you are satisfied with the details of the new application,

Click on **OK**

Cloning will automatically populate a number of relevant fields within the Device Application.

If you made a mistake or are not satisfied that the ARTG Number was the correct choice

Click on **Cancel**

You then have the option of
Repeating the Search and Clone Function
Or

Deleting/ Clearing the ARTG number from the ARTG number field.

Application Class Details:



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NOTE: All Included-Medical Devices (Export Only) are classified as Class 1 and the system will automatically identify Included-Medical Devices (Export Only) as Class 1.

Other Therapeutic Goods do not have [Class Details](#).

Notes on how to enter a **Device Application for a Medical Device – included - Class 1** is documented separately.

Manufactures Intended purpose of the device:

Is a free text field.

Type in a brief but thorough description of the device and its intended purpose.

Specific Details for your Device Application

At the Specific Details portion of Screen 1 you are presented with a series of questions that must be answered in relation to your device.

How you answer these questions will determine the content of proceeding screens.

All the following questions can be answered either Yes or No.

Click on the radio buttons Yes No to answer each question.

Answer the first seven (7) questions first.

Specific Details	
★ Is the device, or any form of the device, supplied sterile:	<input type="radio"/> Yes <input type="radio"/> No
★ Is the device intended to be invasive:	<input type="radio"/> Yes <input type="radio"/> No
★ Is the device, or any form of the device, intended for single use:	<input type="radio"/> Yes <input type="radio"/> No
★ Is the device an active device:	<input type="radio"/> Yes <input type="radio"/> No
★ Does the device contain material or ingredients of microbial origin:	<input type="radio"/> Yes <input type="radio"/> No
★ Does the device contain material or ingredients of recombinant origin:	<input type="radio"/> Yes <input type="radio"/> No
★ Does the device contain material or ingredients manufactured or formulated using a genetically modified organism:	<input type="radio"/> Yes <input type="radio"/> No

The next question relates to the use of contents of Human Origin.

★ Does the device contain material or ingredients of Human Origin:	<input type="radio"/> Yes <input type="radio"/> No
--	--

If you answer, Yes, you are required to answer an additional question –

★ Does the device contain Human Blood or its components:	<input type="radio"/> Yes <input checked="" type="radio"/> No
--	---

The next questions relates to how the device is packaged.

You must answer yes to one of these questions to determine the ‘product type’ of your device.

Following the determination of your ‘product type’, you will be presented with 2 to 4 further questions.



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Device Product Type

1. If you have selected

Medical Device - Included (Export Only)



At [Application for](#): you will be presented with the following three (3) options.

<p>★ Does the device consist of:</p> <p>:</p>	<p><input type="radio"/> Products packaged as a procedure pack</p> <p><input type="radio"/> Products packaged as a system</p> <p><input checked="" type="radio"/> Single product only</p>
---	---

2. If you have selected any of the following

Other Therapeutic Good - Registered disinfectant
Other Therapeutic Good - Registered IVD
Other Therapeutic Good - Registered other (i.e. human origin products)
Other Therapeutic Good - Listed disinfectant
Other Therapeutic Good - Listed IVD
Other Therapeutic Good - Listed other
Other Goods - not medical devices - Export Only

At [Application for](#): you will be presented with the following two (2) options.

<p>★ Does the device consist of:</p>	<p><input type="radio"/> Products packaged as a kit</p> <p><input checked="" type="radio"/> Single product only</p>
--------------------------------------	---

NOTE: The selection of either

Products packaged as a procedure pack

OR

Products packaged as a kit

Will result in the same sequence of questions being asked. For the purpose of this exercise, treat the selection as one and the same option.



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Device Single Product

Selecting Single Product Only

Single product only

The first question relates to materials or ingredients of Animal Origin
If you answer Yes to this question, you will be asked to select
[Animal Species](#)

And

[Country of Origin](#)

From drop down lists

★ Does the device contain material or ingredients of Animal Origin rendered non-viable.	<input checked="" type="radio"/> Yes <input type="radio"/> No
★ Animal Species:	<input type="text"/>
★ Country of Origin:	<input type="text"/>

You will need to answer either Yes or No as to whether the device is
Medicated or Formulated.

★ Is the device medicated:	<input checked="" type="radio"/> Yes <input type="radio"/> No
★ Is the device formulated:	<input checked="" type="radio"/> Yes <input type="radio"/> No

Once you have answered all the questions presented

Click on [Next](#)

To take you to Page 2 of Device Application

**How you answer these questions will determine the content of
proceeding screens.**

Device Procedure Pack

Selecting Products Packaged as a Procedure Pack

Products packaged as a procedure pack

Or

Products packaged as a kit

Answer **Yes** or **No** to the following four (4) questions

<p>★ Does any component in the procedure pack, kit or system contain material or ingredients of Animal Origin rendered non-viable?* <small>*If 'Yes' please enter the animal origin details for each relevant component on page 4b</small></p> <p>★ Does the product contain a medicine that is supplied separately in the Australian Market:</p> <p>★ Does the product contain a medical device which incorporates a medicine as an integral part and that has an action ancillary to the device:</p> <p>★ I declare that this device contains only components that are medical devices which have been individually certified.</p>	<input checked="" type="radio"/> Yes <input type="radio"/> No	<input checked="" type="radio"/> Yes <input type="radio"/> No	<input checked="" type="radio"/> Yes <input type="radio"/> No
--	---	---	---

Once you have answered all the questions presented

Click on **Next**

To take you to Page 2 of Device Application

How you answer these questions will determine the content of proceeding screens.



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Device Packaged as a System

Selecting Products Packaged as a System

Products packaged as a system

Answer Yes or No to the following three (3) questions.

<p>★ Does any component in the procedure pack, kit or system contain material or ingredients of Animal Origin rendered non-viable?*</p> <p><small>*If 'Yes' please enter the animal origin details for each relevant component on page 4b</small></p>	<input checked="" type="radio"/> Yes <input type="radio"/> No
<p>★ Is the device medicated:</p>	<input checked="" type="radio"/> Yes <input type="radio"/> No
<p>★ Is the device formulated:</p>	<input checked="" type="radio"/> Yes <input type="radio"/> No

Once you have answered all the questions presented

Click on **Next**

To take you to Page 2 of Device Application

How you answer these questions will determine the content of proceeding screens.

Device Application Medical Device – Included – (Class 1) - Page 1

The Device Application form is used to submit a Medical Device-Included Class 1 onto the Australian Register of Therapeutic Goods (ARTG).

The form is made up of 5 pages which may vary in content – depending on how you answer questions presented. The system will only display the pages relevant to the Device Application being submitted.

NOTE:

(Click on the  for an explanation of the current screen or field)

(Click on the  for an explanation of a question)

An [Application Identifier](#) will be generated automatically when you save, close, validate, or go to the next page of the form).

A number of the fields will generate automatic information. This is based on your Log-In details.

[Agent Details](#) will only be displayed if you have an Agent Log-In.

To commence a Device Application Medical Device – Included (Class 1)

Select [Portal – Therapeutic Goods Administration](#)

When the screen drops down

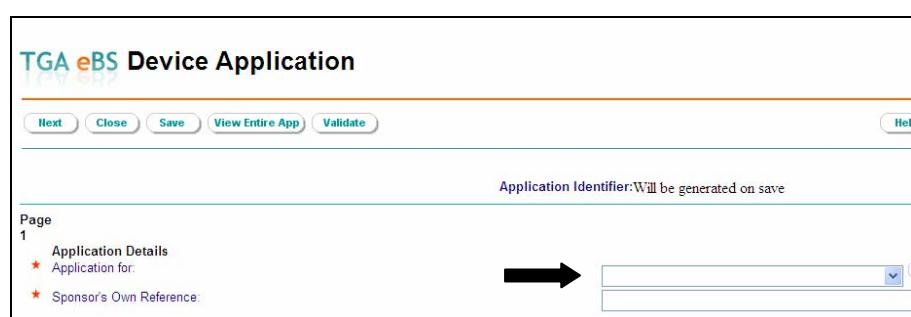
Select [Create Applications and submissions](#)

Select [Medical Device](#)

then

Click on [Device Application](#) to open the link to

This brings you to the first page of **Device Application**



TGA eBS Device Application

Next Close Save View Entire App Validate Help

Application Identifier: Will be generated on save

Page 1

Application Details

* Application for: 

* Sponsor's Own Reference:



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Application Details

At **application for:** from the drop down list select

Medical Device - Included

This will create of your Application Identifier: number at the top of the screen. Take note of this number.

TGA eBS Device Application

Application Identifier: DV-2008-DA-56309-3

Page 1

Application Details

Application for: Medical Device - Included

Sponsor's Own Reference: Putting in sponsor's own reference

At the Field **Sponsor's Own Reference:**

Type in your own reference details.

Sponsor Details

Agent Name:

will be automatically selected (based on your log-In);

Sponsor Name:

will be automatically selected (based on your log-In);

Or

you will need to make a selection from the drop down **Sponsor Name:** list

The **Contact Name** and **Contact Email** will be automatically generated once the **Sponsor Name:** is selected.

Sponsor Details
Agent name: TGA Demo A
★ Sponsor name: TGA Demo A
★ Contact name: Device Demo
Contact email: Devicedemo@tga.com.au

Address Details

Address(es) are automatically generated, based on your (log-In)

You may have more than one address. If you have more than one address, ensure that your Billing Address and your Regulatory Address are stated separately in the correct field.

At **Billing Address:**

Select your correct address for billing/account purposes from the drop down list.

At **Regulatory Correspondence Address:**

Select your correct address for Compliance/Regulatory purposes from the drop down list.

Billing address:	PO Box WODEN ACT 2606
Regulatory correspondence address:	PO Box WODEN ACT 2606
	PO Box WODEN ACT 2606

The next step, Create a new Register, is already selected for you.

This application is to:	<input checked="" type="radio"/> Create a new register The new application can be based on an existing application then 'cloning' to populate the application details.
-------------------------	---

Cloning an ARTG Inclusion For a Device Application

Note: If you already have a similar medical device included on the ARTG, you can 'Clone' or copy the details of that ARTG entry and change any relevant details. ARTG entries - Included Medical Device (Export only) and Other Goods (Registered, listed and Export only) can not be cloned. You can choose to leave this field empty and go to the next step – [Manufacturer's intended purpose for the device](#):

At [ARTG Number](#):

You can leave this field empty.

If you have a similar ARTG inclusion and you know the [ARTG Number](#):
Type the code in the ARTG Number box, or

Click on [Search](#)

This will bring up a Code Picker list of your ARTG devices to choose from.

Code Picker - ARTG ID

Search for...		Go!	Reset
153429	TGA Demo A - Cardiac mapping system catheter, oesophageal, reprocessed	Class 1	Biotronik AG
153326	TGA Demo A - Demonstration of Class III ARTG Certificate UPI - Catheter guide wire	Class III	Cipan
153430	TGA Demo A - Depressor, tongue	Class 1	Boston Scientific Precision Vascular
153414	TGA Demo A - Drainage bag	Class 1	Medko Med

1 to 4 of 4 records

[Clear Field](#) [Cancel](#)

The Code Picker allows you to:

Narrow the field of search by entering the first few numbers of the ARTG number (if known) or a few characters in the name of the device or manufacturer and pressing [Go!](#)
OR

Scroll through the entire list to find the ARTG entry.

You can move through the pages of ARTG Inclusions by using the following arrow keys.



Clicking on **Reset**

Will reset the search and re-list all your ARTG entries for that classification.

Once you have located the ARTG entry, point to and click on the correct line.

This immediately takes your selected ARTG code number and inserts it into the **ARTG Number** box on your application.

If you make a mistake or need to make a change,

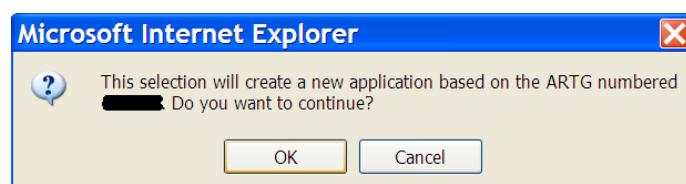
Click on **Search**

This will return you to the Code Picker list where you can make an alternative selection.

Once you have the ARTG inclusion you wish to copy details of

Click on **Clone**

The following pop up, confirmation screen appears.



If you are satisfied with the details of the new application,

Click on **OK**

This will automatically populate a number of relevant fields within the Device Application.



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If made a mistake or are not satisfied that the ARTG Number was the correct choice

Cancel

Click on

You then have the option of
Repeating the Search and Clone Function

Or

Deleting/ Clearing the ARTG number from the ARTG number field

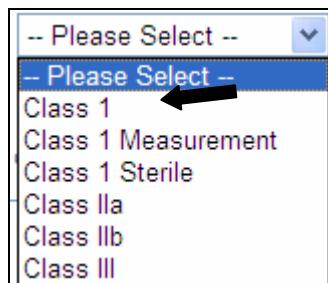
Application Class Details:

NOTE:

When you select **Medical Device – Included** at Application For and then Class 1 in Application Class Details: A separate set of questions are asked which are specific to **Medical Device – Included (Class 1)**.

At the Field **Class**: you are required to select an option from the drop down list.

As we are working on a Medical Device Included (Class 1) application
Select Class 1:



You will notice that the screen name is changed from
TGA e-Business Device Application
To
TGA e-Business Device Application Auto Inclusion Class 1

The questions at the bottom of the screen change – they are specific for a Class 1 – Medical Device – Included.

TGA eBS Device Application Auto Inclusion Class 1

Application Identifier: DV-2008-DA-56368-3

Page 1

Application Details

Application for:

Manufactures Intended purpose of the device:

Is a free text field.

Type in a brief but thorough description of the device and its intended purpose.



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Device Product Characteristics of your Device Application

At Device Product Characteristics, you will be presented with a range of questions to which you must answer Yes or No.

NOTE: You are legally required to supply accurate responses to the Device Product Characteristic's questions. Therefore you must ensure that you are fully informed before entering any information. Penalties apply for false or misleading information.

Be aware that the following list of questions is not a definitive list of questions. TGA may make changes to the questions and add alternative or supplementary questions.

Device Product Characteristics	
Please note that you are legally required to supply accurate responses to the device product characteristic's questions, therefore you must ensure that you are fully informed before entering information. Penalties apply for false or misleading information.	
Is the device a single product only? (Q01)	<input type="radio"/> Yes <input type="radio"/> No
Is this medical device presented as a procedure pack? (Q38)	<input type="radio"/> Yes <input type="radio"/> No
Is the product presented as a system? (Q39)	<input type="radio"/> Yes <input type="radio"/> No
Is the device, or any form of the device, supplied sterile? (Q03)	<input type="radio"/> Yes <input type="radio"/> No
Does the device have a measuring function? (Q04)	<input type="radio"/> Yes <input type="radio"/> No
Is the device, or any form of the device, intended for single use? (Q43)	<input type="radio"/> Yes <input type="radio"/> No
Does the device contain material or ingredients of human origin? (Q33)	<input type="radio"/> Yes <input type="radio"/> No
Does the device contain materials of recombinant origin? (Q25)	<input type="radio"/> Yes <input type="radio"/> No
Does the device contain materials of animal origin? (Q27)	<input type="radio"/> Yes <input type="radio"/> No
Is the device intended to be non-invasive? (Q44)	<input type="radio"/> Yes <input type="radio"/> No
Is the device intended to be invasive via a body orifice? (Q09)	<input type="radio"/> Yes <input type="radio"/> No
Is the device intended to be surgically invasive (i.e. will it penetrate the skin)? (Q05)	<input type="radio"/> Yes <input type="radio"/> No
Is the device an active device? (Q17)	<input type="radio"/> Yes <input type="radio"/> No
Does the device control, monitor and/or influence an active medical device classified as Class IIb or higher? (Q21)	<input type="radio"/> Yes <input type="radio"/> No
If the device is a single product does it incorporate a medicine? (Q22)	<input type="radio"/> Yes <input type="radio"/> No
If the device is a procedure pack does it contain a separate medicine(s)? (Q29)	<input type="radio"/> Yes <input type="radio"/> No
Is the device formulated? (Q32)	<input type="radio"/> Yes <input type="radio"/> No
Is the device intended by the manufacturer to be used for contraception or the prevention of sexually transmitted diseases? (Q47)	<input type="radio"/> Yes <input type="radio"/> No
Is the device intended by the manufacturer to be used for disinfecting, cleaning, rinsing or hydrating contact lens? (Q48)	<input type="radio"/> Yes <input type="radio"/> No
Is the device intended by the manufacturer to be used for disinfecting another medical device other than a device used only to clean by means of physical action? (Q49)	<input type="radio"/> Yes <input type="radio"/> No
Is the device intended by the manufacturer to be non-active and record X-ray diagnostic images? (Q50)	<input type="radio"/> Yes <input type="radio"/> No
Is the device intended by the manufacturer to be used as a blood bag? (Q51)	<input type="radio"/> Yes <input type="radio"/> No

Individual questions may result in the presentation of further questions.

If you are unsure as to what a question means

Click on

Which will provide information on that question.

How you answer these questions will determine the content of proceeding screens.

Once you have answered Yes or No to each question

Click on

This takes you to page 2 of Device Application.



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1. Device Application Page - 2A (Export Only)

NOTE:

If your application is for, or at Page 1 you selected:

- **Medical Device – Included (Export Only); or**
- **Other Goods – not medical device - Export Only**

Page 2A will appear as follows

Manufacturing Details (Class 1) Existing Manufacturer

To enter your Manufacturer Name

Click on **Search**

This will bring up the following screen

By typing in the first 3 to 4 letters of your manufacturer and

Clicking **Search**

You will be provided with a list of Manufacturers.

Make your selection by pointing and clicking on your Manufacturer and

Clicking **Add to Application**



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This takes your selection back to the **Device Application Screen**

Page 2A - Manufacturing Details (Class

1)

★ Manufacturer name:

Cipan (Portugal)[22619]

Search **Remove**

★ Manufacturer address:

Vala do Carregado Alenquer Lisbon 2580 Portugal S [57590]

Manufacturing Details (Class 1) New Manufacturer

If you are entering a new Manufacturer you will be required to type in your **New Manufacturer Name:**

New Manufacturer Address:

And from the drop down list, select

New Manufacturer Country:

★ New Manufacturer Name:
★ New Manufacturer Address:
★ New Manufacturer Country:

Manufacturing Details - Export Names

If your application is for an Export Only Medical Device, you will be presented with the following field.

★ Export Name(s):

Export Names:

In this free text field, type in the Product Name (or Names) to be used overseas.

Note: If you have more than one export name, press 'ENTER' after you have typed each export name to take you to the next line.

Searching for GMDN

At the GMDN **Code and Description:**

search for the GMDN (Global Medical Device Nomenclature) code.

Click on

Search

The following screen will appear

The GMDN is a nomenclature system for medical devices for the purpose of exchange of regulatory data. The coding follows strict rules where the term is made up of a base concept (noun or phrase) followed by one or more qualifiers. For searching purpose, the system also employs synonyms.

Search: GMDN Text: **Go** (Minimum 3 characters to search for text)
*Keywords including AND, AND NOT and OR may be used to refine your search

GMDN Code:

View Definition Enter a search.....



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At the **GMDN Text:** Field

Type in at least the first three characters of the device

Or,

At the **GMDN Code:** Field

Type in the GMDN, then



Press

The GMDN is a nomenclature system for medical devices for the purpose of exchange. It follows strict rules where the term is made up of a base concept (noun or phrase) for the searching purpose, the system also employs synonyms.

Search: GMDN Text: (Minimum 3 characters)
*Keywords including AND, AND NOT and OR may be used

GMDN Code:

This brings up a list of all GMDN's containing those three letters.

If you select the incorrect line/item, Scroll to the bottom of the screen and



Click on

Cancel

You will then need to



Click on

Search

And start your search again.

To Select the GMDN item, point to and click on required item.

Scroll to the bottom of that screen and



Click on

OK

Suture, cotton[15872]
Suture, iodized[15873]
Suture, linen[13902]

The "Synonym" label identifies terms by common usage descriptions that link to a primary GMDN term. When the synonym is selected, the primary term is displayed through the "View Definition" and it is the primary code that is passed to the DEAL form.

This takes your selection back to the **Device Application Screen**.

If you are then satisfied with the information on this screen



Click on

Next

To move to the next screen.

Page 2A - Manufacturing Details (Class 1)

★ Manufacturer name: Search Remove

★ Manufacturer address: Search

★ Export name(s):
For more than one export name,
please type them on a separate line
using the ENTER key.

Export Name 1
Export Name 2

★ GMDN code and description: Search

Previous Next Close Save View Entire App Validate

↓

How you have answered questions on screen 1 will determine which screen is presented next.

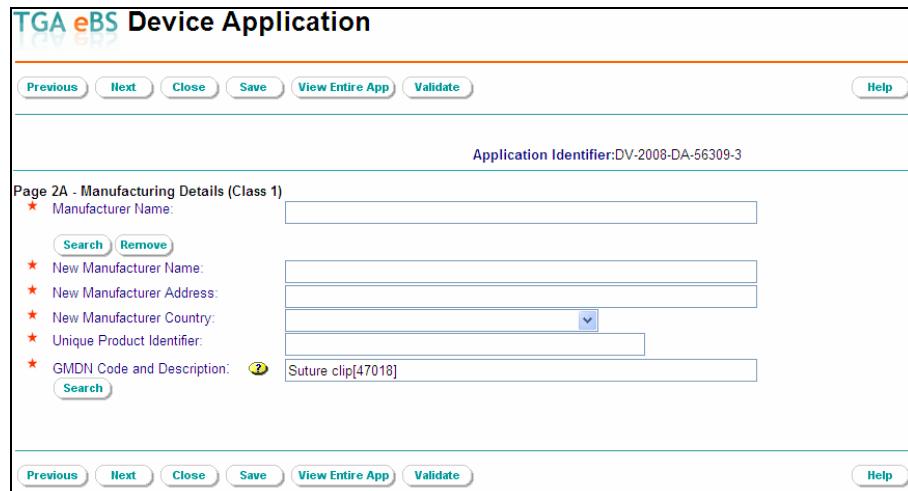
2. Device Application Page 2A (Other Therapeutic Goods)

NOTE:

If your application is for, or at Page 1 you selected:

- **Other Therapeutic Goods – Registered – disinfectant**
- **Other Therapeutic Goods – Registered – other (i.e. human origin products)**
- **Other Therapeutic Goods – Listed – disinfectant**
- **Other Therapeutic Goods – Listed – other**

Page 2A will appear as follows:

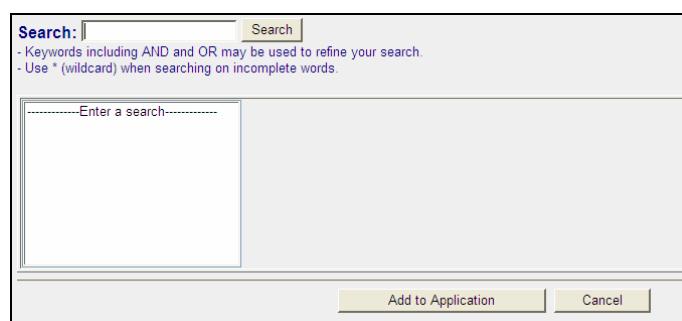


Manufacturing Details (Class 1) Existing Manufacturer

To enter your Manufacturer Name

Click on **Search**

This will bring up the following screen



By typing in the first 3 to 4 letters of your manufacturer and

Clicking **Search**

You will be provided with a list of Manufacturers.

Make your selection by pointing and clicking on your Manufacturer and

Clicking **Add to Application**

This takes your selection back to the **Device Application** Screen

Page 2A - Manufacturing Details (Class

1)

★ Manufacturer name:	Cipan (Portugal)[22619]
<input type="button" value="Search"/> <input type="button" value="Remove"/>	
★ Manufacturer address:	Vala do Carregado Alenquer Lisbon 2580 Portugal S [57590]

Manufacturing Details (Class 1) New Manufacturer

If you are entering a new Manufacturer you will be required to type in your

[New Manufacturer Name:](#)

[New Manufacturer Address:](#)

And from the drop down list, select

[New Manufacturer Country:](#)

★ New Manufacturer Name:	
★ New Manufacturer Address:	
★ New Manufacturer Country:	<input type="button" value=""/>

The UPI is the combination of words, numbers, symbols or letters assigned by the manufacturer to uniquely identify the device. Type in a description or product identifier for your device at

[Unique Product Identifier:](#)

★ Unique Product Identifier:	
------------------------------	--

Searching for GMDN

At the

[GMDN Code and Description:](#)

search for the GMDN (Global Medical Device Nomenclature) code

Click on

The following screen will appear

<p>The GMDN is a nomenclature system for medical devices for the purpose of exchange of regulatory data. The coding follows strict rules where the term is made up of a base concept (noun or phrase) followed by one or more qualifiers. For searching purpose, the system also employs synonyms.</p> <p>Search: GMDN Text: <input type="text"/> <input type="button" value="Go"/> (Minimum 3 characters to search for text) *Keywords including AND, AND NOT and OR may be used to refine your search</p> <p>GMDN Code: <input type="text"/></p>	
<input type="button" value="View Definition"/>	-----Enter a search-----

At the [GMDN Text:](#) Field

Type in at least the first three characters of the device

Or,

At the [GMDN Code:](#) Field

Type in the GMDN, then

Press



The GMDN is a nomenclature system for medical devices for the purpose of exchange. It follows strict rules where the term is made up of a base concept (noun or phrase) followed by qualifiers. For searching purpose, the system also employs synonyms.

Search: GMDN Text: **Go** (Minimum 3 characters)
*Keywords including AND, AND NOT and OR may be used

GMDN Code:

View Definition

Clip, surgical, suture[38143]
Endotherapy device, suturing[34078]
Guide, suture[36129]
Hook, surgical, tonsil, suturing[33454]
Needle, suture, <specify>[34604]
Needle, suture, aneurysm[34608]
Needle, suture, arthroscopic surgery, single-use[44664]

This brings up a list of all GMDN's containing those three letters.

If you select the incorrect line/item, Scroll to the bottom of the screen and
Click on **Cancel**
You will then need to
Click on **Search**
And start your search again.

To Select the GMDN item, point to and click on required item.

Scroll to the bottom of that screen and

Click on **OK**

Suture, iodized[15873]
Suture, linen[13902]

The "Synonym" label identifies terms by common usage descriptions that link to a primary GMDN term. When the synonym is selected, the primary term is displayed through the "View Definition" and it is the primary code that is passed to the DEAL form.

OK **Cancel**

This takes your selection back to the **Device Application Screen**.

If you are then satisfied with the information on this screen

Click on **Next**

To move to the next screen.

TGA eBS Device Application

Page 2A - Manufacturing Details (Class 1)

★ Manufacturer name: Search Remove

★ Manufacturer address: Search

★ Unique product identifier: ?

★ GMDN code and description: ?

Search

Previous Next Close Save View Entire App Validate



How you have answered questions on screen 1 will determine which screen is presented next.

3. Device Application - Page 2A Medical Device – Included (Class 1)

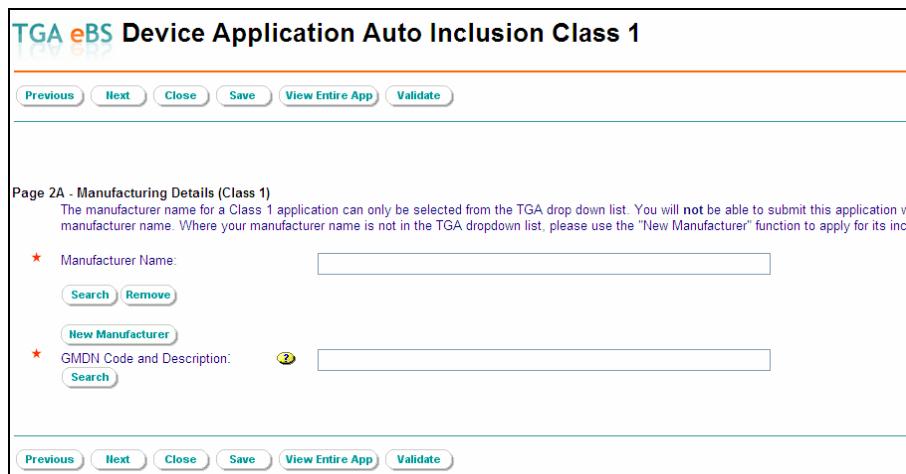
NOTE:

If your application is for, or at Page 1 you selected:

- Medical Device – Included

And then selected your Application Class Details as **Class 1**

Page 2A will appear as follows:



TGA eBS Device Application Auto Inclusion Class 1

Page 2A - Manufacturing Details (Class 1)

The manufacturer name for a Class 1 application can only be selected from the TGA drop down list. You will not be able to submit this application without a manufacturer name. Where your manufacturer name is not in the TGA dropdown list, please use the "New Manufacturer" function to apply for its inclusion.

★ Manufacturer Name:

★ GMDN Code and Description:

Previous **Next** **Close** **Save** **View Entire App** **Validate**

Manufacturing Details (Class 1) Existing Manufacturer

To enter your Manufacturer Name

Click on **Search**

This will bring up the following screen



Search:

- Keywords including AND and OR may be used to refine your search.
- Use * (wildcard) when searching on incomplete words.

Enter a search...

By typing in the first 3 to 4 letters of your manufacturer and

Clicking **Search**

You will be provided with a list of Manufacturers.

Make your selection by pointing and clicking on your Manufacturer and Click **Add to Application**

This takes your selection back to the **Device Application** Screen and adds the address to the Manufacturer Address field.



TGA eBS Device Application Auto Inclusion Class 1

Previous Next Close Save View Entire App Validate

Page 2A - Manufacturing Details (Class 1)

Application Identifier: DV-2008-DA-56901-3

The manufacturer name for a Class 1 application can only be selected from the TGA drop down list. You will not be able to submit this application without a valid manufacturer name. Where your manufacturer name is not in the TGA dropdown list, please use the "New Manufacturer" function to apply for its inclusion.

★ Manufacturer Name:

★ Manufacturer Address:

★ GMDN Code and Description:

Previous Next Close Save View Entire App Validate

Manufacturing Details (Class 1) New Manufacturer

If the manufacturer is new (does not appear on the TGA Client Database) you will need to have the Manufacturer details added to the database before you can submit your application.

Click on **New Manufacturer**
The following window will open.

Request for entry of a new manufacturer on the TGA Client database

This email new manufacturer request facility will be sent to the corporate management area of TGA for entry of the manufacturer name and address details into the TGA Client database. The attached or supporting information will be used to help resolve duplicate names or other administrative anomalies. A return email will be used to help resolve any name and address concerns.

The request is for
Contact person
Email
New manufacturer name:
Manufacturer address:
Country:

Please attach documentation containing the name and address details to support the administrative request. Up to three separate attachments can be added to this form, but only one is mandatory.

You should save your Class 1 medical device application as a draft till notified that your new manufacturer has been entered into the TGA Client database. You will receive a return email indicating the name is available for inclusion in your Class 1 application.

Done Internet

You will need to type in

The New Manufacturer Name
The New Manufacturer Address, and
Select the Manufacturer Country from the drop down list.



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You will need to provide documents proving the manufacturer address details. These can be attached electronically.

Click on [Browse...](#)

This will access your own computer system where you can select the relevant documents relating to the manufacturer. The documents will be added to the Request for entry of a new manufacturer on the TGA Client Database.

Once you have completed filling out the new manufacturer details, you should print a copy of your request.

Click on [Print](#)

And follow the prompts to print the request.

Once you have printed your request, you can then forward it to the TGA.

Click on [Send](#)

This takes you back to page 2A of your Device Application.

At this point, you should [Save](#) and [Close](#) your application. Until the new manufacturer details are acknowledged by the TGA, you will not be able to submit the application. You should receive an e-mail from the TGA confirming the receipt of your New Manufacturer details.

Take note of your Application Identifier Number for accessing your draft application once your new manufacturer has been included on the TGA database.

At a later date, you will receive an e-mail from the TGA advising that the new manufacturer has been added to the database. You will then be able to access your Draft Application and Included Medical Device – Class 1, add the manufacturer then continue with your application.

Device System Name is a free text field – type in the Device System Name used/to be used.

Note: Device System Name field will only be shown if products packaged as a system was selected on previous page)

Searching for GMDN

At the

GMDN Code and Description:

search for the GMDN (Global Medical Device Nomenclature) code

Click on [Search](#)



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The following screen will appear

The GMDN is a nomenclature system for medical devices for the purpose of exchange of regulatory data. The coding follows strict rules where the term is made up of a base concept (noun or phrase) followed by one or more qualifiers. For searching purpose, the system also employs synonyms.

Search: GMDN Text: **Go** (Minimum 3 characters to search for text)
*Keywords including AND, AND NOT and OR may be used to refine your search

GMDN Code:

View Definition Enter a search

At the **GMDN Text:** Field

Type in at least the first three characters of the device
Or,

At the **GMDN Code:** Field

Type in the GMDN, then



Press

The GMDN is a nomenclature system for medical devices for the purpose of exchange of regulatory data. The coding follows strict rules where the term is made up of a base concept (noun or phrase) followed by one or more qualifiers. For searching purpose, the system also employs synonyms.

Search: GMDN Text: **Go** (Minimum 3 characters to search for text)
*Keywords including AND, AND NOT and OR may be used to refine your search

GMDN Code:

View Definition

Clip, surgical, suture[38143]
Endotherapy device, suturing[34078]
Guide, suture[36129]
Hook, surgical, tonsil, suturing[33454]
Needle, suture, <specify>[34604]
Needle, suture, aneurysm[34608]
Needle, suture, arthroscopic surgery, single-use[44664]

This brings up a list of all GMDN's containing those three letters.

If you select the incorrect line/item, Scroll to the bottom of the screen and
Cancel
Click on **Cancel**
You will then need to
Search
Click on **Search**
And start your search again.

To Select the GMDN item, point to and click on required item.

Scroll to the bottom of that screen and

Click on **OK**

Suture, iodized[15873]
Suture, linen[13902]

The "Synonym" label identifies terms by common usage descriptions that link to a primary GMDN term. When the synonym is selected, the primary term is displayed through the "View Definition" and it is the primary code that is passed to the DEAL form.

→ **OK** **Cancel**

This takes your selection back to the **Device Application** Screen.

If you are then satisfied with the information on this screen

Click on

Next

To move to the next screen.

Page 2A - Manufacturing Details (Class 1)

The manufacturer name for a Class 1 application can only be selected from the TGA drop down list. You will not be able to submit this application without a valid manufacturer name. Where your manufacturer name is not in the TGA dropdown list, please use the "New Manufacturer" function to apply for its inclusion

Application Identifier DV-2008-DA-56901-3

★ Manufacturer Name:

★ Manufacturer Address:

★ GMDN Code and Description:

Previous **Next** **Close** **Save** **View Entire App** **Validate**

How you have answered questions on screen 1 will determine which screen is presented next.

1. Device Application - Page 2B

If your application is for, or at Page 1 you selected:

- Other Therapeutic Goods – Registered – IVD
- Other Therapeutic Goods – Listed – IVD

Page 2B will appear as follows:

Manufacturing Details Other Therapeutic Goods Page 2B

TGA eBS Device Application

Page 2B - Manufacturing Details (Other Classes)

Application Identifier DV-2008-DA-56901-3

★ Select manufacturer for evidence:

★ Manufacturer address as on evidence:

★ GMDN code and description:
For Information Only
 Certification issued by:

★ Unique product identifier:
 The UPI is the unique name that is assigned to the product. Note: This field is limited to 130 characters.

★ Functional description:
 The functional description should describe the operation of the medical device, not its composition.

At **Select Manufacturer for Evidence**: click on the drop down list and scroll through to find the relevant Manufacturer.

Click on the Manufacturer.

This takes your selection back to Page 2B. Notice that an additional field **Manufacturer Evidence Number**: has been added to the screen.

From this drop down list a list of Manufacturer Evidence Numbers are provided for the chosen manufacturer.

At **Manufacturer Evidence Number:** click on the drop down list and scroll through to find the relevant Manufacturer Evidence to support the application.

Once you have selected the relevant Evidence number, you will notice that the address relating to that Evidence is provided automatically.

The system will automatically provide the **Manufacturer Address as on Evidence.** This address is the address which corresponds with the selected Evidence.

GMDN Code and Description gives you the list of the GMDN Codes which are on that Manufacturer Evidence. Select the relevant GMDN code from the drop down list.

Note that at

Certification Issued By:

Details are automatically provided once you have selected your manufacturer and GMDN Code.

The UPI is the combination of words, numbers, symbols or letters assigned by the manufacturer to uniquely identify the device. Type in a description or product identifier for your device **At Unique Product Identifier:**

At **Functional Description** type in a description of how the device will operate or be used (Not the composition of the device).

Click on The button is a light blue rounded rectangle with the word 'Next' in white, bold, sans-serif font.

Which will take you to the next 'relevant' screen.

How you have answered questions on page 1 will determine which screen is presented next.



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2. Device Application - Page 2B

If your application is for, or at Page 1 you selected:

- Medical Device – Included

And the **Application Class Details** given were one of the following

- **Class 1 Measurement;**
- **Class 1 Sterile;**
- **Class IIa;**
- **Class IIb; or**
- **Class III**
- **AIMD**

And, you identified that your device is **Packaged as a System**

Page 2B will appear as follows

Manufacturing Details - Medical Device – Included (Other Classes), Packaged as a System

TGA eBS Device Application

[Previous](#) [Next](#) [Close](#) [Save](#) [View Entire App](#) [Validate](#)

Page 2B - Manufacturing Details (Other Classes)

★ **Select Manufacturer for Evidence:** Only manufacturers with certificates which cover the type and/or class of this application (Class IIa) are shown

★ **Manufacturer Evidence Number:** Only certificates which cover the type and/or class of this application (Class IIa) are shown

★ **Manufacturer Address as on Evidence:**

★ **Device System Name:**

★ **GMDN Code and Description:** For Information Only

For Information Only
Certification Issued By:

Classes on the Evidence:

Class of this Application: Class IIa

At **Select Manufacturer for Evidence**: click on the drop down list and scroll through to find the relevant Manufacturer.

Click on the Manufacturer.

This takes your selection back to Page 2B. Notice that an additional field **Manufacturer Evidence Number**: has been added to the screen.

From this drop down list a list of Manufacturer Evidence Numbers are provided for the chosen manufacturer.

At **Manufacturer Evidence Number**: click on the drop down list and scroll through to find the relevant Manufacturer Evidence to support the application.

Once you have selected the relevant Evidence number, you will notice that the address relating to that Evidence is provided automatically.

Device System Name is a free text field – type in the Device System Name used/to be used.

GMDN Code and Description gives you the list of the GMDN Codes which are on that Manufacturer Evidence. Select the relevant GMDN code from the drop down list.

Note that at

Certification Issued By:

Classes on Evidence: and

Class of this Application:

Details are automatically provided once you have selected your manufacturer and GMDN Code.

Additional Fields Class III/AIMD

The UPI is the combination of words, numbers, symbols or letters assigned by the manufacturer to uniquely identify the device. Type in a description or product identifier for your device at **Unique Product Identifier:**

At **Functional Description** type in a description of how the device will operate or be used (Not the composition of the device).

At **Total number of Devices Covered:** Type in the number of devices to be covered by this Application.

From the drop down list at **Variant Type:** select the type of variant/change to the device.

Functional Description: * The functional description should describe the operation of the medical device, not its composition.	Nil variant (as 1 device) Opening width (mm) Product name (see guidance docs) Quantity/pack Radiopacity Shape Shape - rectangular Shape - round Shape - square Shape - triangular Shape (of tip) Size (cm)	document on the TGA website of the device. The range
Total number of Devices Covered: Help An explanation of acceptable variants and their range should be recorded. These should be recorded in the 'Variant Range' field.		
Variant Type:		
Variant Range:		

Once you have selected your Variant Type, type in the Variant Range.

Click on **Add**

This adds your device Variants to the Variant list at the bottom of the screen



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Variant List		
#	Variant Type	Variant Range
1.	Gauge (mm)	1mm

To remove item number from list:

You can continue to build the variants to your device for repeating adding the additional Variant Type and Range.

If you make a mistake or need to make an amendment to your variant list, Click on the drop down list



Point to and click on the line number of the item that needs to be removed, Click on

Once you have completed adding to your variant list

Click on

Which will take you to the next 'relevant' screen.

How you have answered questions on page 1 will determine which screen is presented next.

3. Device Application - Page 2B

If your application is for, or at Page 1 you selected:

- Medical Device – Included

And the **Application Class Details** given were one of the following

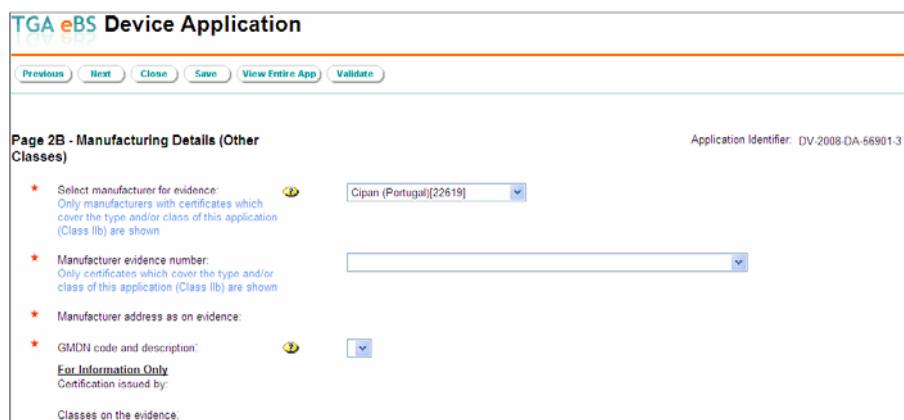
- **Class 1 Measurement;**
- **Class 1 Sterile;**
- **Class IIa;**
- **Class IIb; or**
- **Class III**
- **AIMD**

And, you identified that your device is:

- **Packaged as a Procedure Pack; or**
- **Single Product Only**

Page 2B will appear as follows.

Manufacturing Details - Medical Device – Included (Other Classes), Procedure Pack or Single Product



At **Select Manufacturer for Evidence**: click on the drop down list and scroll through to find the relevant Manufacturer.

Click on the Manufacturer.

This takes your selection back to Page 2B. Notice that an additional field **Manufacturer Evidence Number**: has been added to the screen.

From this drop down list a list of Manufacturer Evidence Numbers are provided for the chosen manufacturer.

At **Manufacturer Evidence Number**: click on the drop down list and scroll through to find the relevant Manufacturer Evidence to support the application.

Once you have selected the relevant Evidence number, you will notice that the address relating to that Evidence is provided automatically.



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GMDN Code and Description gives you the list of the GMDN Codes which are on that Manufacturer Evidence. Select the relevant GMDN code from the drop down list.

Note that at

Certification Issued By:

Classes on Evidence: and

Class of this Application:

Details are automatically provided once you have selected your manufacturer and GMDN Code.

The UPI is the combination of words, numbers, symbols or letters assigned by the manufacturer to uniquely identify the device. Type in a description or product identifier for your device at **Unique Product Identifier:**

At **Functional Description** type in a description of how the device will operate or be used (Not the composition of the device).

At **Total number of Devices Covered:** Type in the number of devices to be covered by this Application.

From the drop down list at **Variant Type:** select the type of variant/change to the device.

Functional Description: * The functional description should describe the operation of the medical device, not its composition.	Nil variant (as 1 device) Opening width (mm) Product name (see guidance docs) Quantity/pack Radiopacity Shape Shape - rectangular Shape - round Shape - square Shape - triangular Shape (of tip) Size (cm)	document on the TGA website of the device. The range
Total number of Devices Covered: Help		
An explanation of accept A variant and its range should be recorded		
Variant Type:		
Variant Range:		

Once you have selected your Variant Type, type in the Variant Range.

Click on

Add

This adds your device Variants to the Variant list at the bottom of the screen

Variant List		
#	Variant Type	Variant Range
1.	Gauge (mm)	1mm

To remove item number from list: **1.** **Remove**

You can continue to build the variants to your device for repeating adding the additional Variant Type and Range.

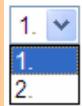


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If you make a mistake or need to make an amendment to your variant list,
Click on the drop down list



Point to and click on the line number of the item that needs to be removed,
Click on **Remove**

Once you have completed adding to your variant list

Click on **Next**

Which will take you to the next 'relevant' screen.

How you have answered questions on page 1 will determine which screen is presented next.



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Device Application - Page 3A

If at Page 1, you selected any Application – **Excluding** Medical Device – Included (Class 1)
AND

If you have answered YES to any question relating to your device being Medicated or Formulated you will be presented with the following screen. Page 3A will be presented as follows.

Medicated or Formulated

In this screen you are required to list all product ingredient(s) for your device.

TGA eBS Device Application

Previous Next Close Save View Entire App Validate

Page 3A - Medicated or Formulated

The Search lookup provides access to a list of ingredients as an 'Australian' approved name.
If the "New Ingredient" option is used, an administrative process will be undertaken to endorse its use.
Please use the 'New' option to add Proprietary Ingredients (PIs) to the list.

Ingredient Name:

New Ingredient Name:

Quantity:

Units:

Ingredient List

#	Ingredient Code	Ingredient Name	Quantity	Units
1	PI0001	Paracetamol	1000	mg

Develop an Ingredient List – Ingredient Name

At [Ingredient Name](#):

Click on

Which will bring up the following Ingredients Search Screen

https://www.ebsacceptance.tga.gov...

Ingredients Search

Search On Whole of field Start of field Any part of the field

Enter Search Terms Go (minimum 3 characters)
 *Keywords including AND and OR may be used to refine your search)

Add it Cancel

.....Enter a Search.....

You can search using the

- entire name of the ingredient (Spelling and spacing must be exact)
- first three letters at the start of the ingredient (the default option)
- any three letters within the ingredient

At **Search on:**

Click the preferred field button

Search On Whole of field Start of field Any part of the field

At **Enter Search Terms:**

Type in the name or part name of your ingredient.

Click on **Go**

This will bring up either your specific ingredient or a list of ingredients.
 (In this instance the letters searched for are 'uten').

All the ingredients listed with 'uten' in the spelling will be listed)

https://www.ebsacceptance.tga.gov...

Ingredients Search

Search On Whole of field Start of field Any part of the field

Enter Search Terms Go (minimum 3 characters)
 *Keywords including AND and OR may be used to refine your search)

Add it Cancel

2-buten-1-ol
 4-(para-Methoxyphenyl)-3-buten-2-one
 Acrylic acid/3-butene-1,2,3-tricarboxylic acid copolymer
 Ceftibutene
 Methylbutene/piperylene copolymer
 Poly (co-methylacrylate - isobutene - monoisopropyl maleate)
 Polybutene
 Polyisobutene - hydrogenated
 Starch - gluten-free wheat

When you find the correct ingredient, point and click on the item then,

Click on **Add it**



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This takes your selection and adds it to Page 3A of the Device Application page.

At [Quantity](#):

Type in the quantity of ingredient used in the device.

At [Units](#):

Select the appropriate unit of measurement for the ingredient from the drop down list.

Once you have the ingredient, the quantity and unit measure

Click on

This adds your ingredient to the [Ingredient List](#) field on Page 3A

You can continue this procedure until you have all the necessary ingredients listed under the [Ingredient List](#).

If you make a mistake or need to remove a line item, at

[To Remove item number from list](#)

Click on the drop down list



Point to and click on the line item that needs to be removed

Click on

This will remove the line item concerned.

Adding a New Ingredient

If your device has a new ingredient (is not present in the ingredient search), you are required to type in the new ingredient at

[New Ingredient Name](#):

Once you have typed in the new ingredient name

At [Quantity](#):

Type in the quantity of ingredient used in the device.

At [Units](#):

Select the appropriate unit of measurement for the ingredient from the drop down list.

Once you have the ingredient, the quantity and unit measure

Click on

This adds your ingredient to the [Ingredient List](#) field on Page 3A.

You can continue this procedure until you have all the necessary ingredients listed under the [Ingredient List](#).



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Finalising your Ingredient List

Once you are satisfied with your Ingredient List (you have added known and new ingredients,

Click on

Next

To take you to the next page of the application.

How you have answered questions on page 1 will determine which screen is presented next.

Device Application - Page 3A – Medical Device – Included (Class 1)

If at Page 1, you selected
Medical Device – Included (Class 1)
AND
If you have answered YES to the question relating to your device being
Medicated or Formulated you will be presented with the following screen.
Page 3A will be presented as follows.

Medicated or Formulated

In this screen you are required to list all product ingredient(s) for your device.

TGA eBS Device Application Auto Inclusion Class 1

Application Identifier: DV-2008-DA-56352-3

Page 3A - Medicated or Formulated

When entering the ingredient(s) for a Class 1 medical device the ingredient name can only be selected from the TGA ingredient drop down list. You will not be able to submit this application without choosing a valid ingredient name. Where your ingredient name is not in the TGA list, please use the "New Ingredient" function to apply for its inclusion as an 'Australian device approved ingredient name'. The proposed name will be reviewed and you will be notified by return email of its inclusion in the TGA ingredient list.

Ingredient Name:

Quantity:

Units:



TGA

THERAPEUTIC GOODS ADMINISTRATION

Develop an Ingredient List – Ingredient Name

At [Ingredient Name:](#)

Click on

[Search](#)

Which will bring up the following Ingredients Search Screen

You can search using the

- entire name of the ingredient (Spelling and spacing must be exact)
- first three letters at the start of the ingredient (the default option)
- any three letters within the ingredient

At [Search on:](#)

Click the preferred field button

[Search On](#) Whole of field Start of field Any part of the field

At [Enter Search Terms:](#)

Type in the name or part name of your ingredient.

Click on [Go](#)

This will bring up either your specific ingredient or a list of ingredients.
(In this instance the letters searched for are 'uten').

All the ingredients listed with 'uten' in the spelling will be listed)



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When you find the correct ingredient, point and click on the item then,
Click on

This takes your selection and adds it to Page 3A of the Device Application page.

At **Quantity**:

Type in the quantity of ingredient used in the device.

At **Units**:

Select the appropriate unit of measurement for the ingredient from the drop down list.

Once you have the ingredient, the quantity and unit measure

Click on

This adds your ingredient to the **Ingredient List** field on Page 3A.

You can continue this procedure until you have all the necessary ingredients listed under the **Ingredient List**.

If you make a mistake or need to remove a line item, at
[To Remove item number from list](#)

Click on the drop down list



Point to and click on the line item that needs to be removed

Click on

This will remove the line item concerned.

When you have completed your list of ingredients,

Click on

To take you to the next page of the application.

Adding a New Ingredient

If your device has a new ingredient (is not present in the ingredient search), you will need to send a request form to the TGA to have the new ingredient details added to the database.

When you select a new ingredient, an electronic e-mail form is produced. You are required to fill out this form with the new ingredient details. The form will be sent automatically to the TGA for review and update of the database.

To add the new ingredient

Click on



TGA

THERAPEUTIC GOODS ADMINISTRATION

This will bring up the following screen.

Note that the Application Identifier Number is already included on the form.

Type in the **Proposed Name** of the ingredient.

At **Chemical Abstract Service (CAS) number** type in the Chemical Abstract Service Number that has been allocated to the chemical.

At **Other names by which the substance may also be known**, you will need to include the Synonyms or other names by which the chemical is known.

The Reference(s) field includes a drop down list of recognised monograph references. Select one or more of these to which you have referred to for recognition of your ingredient.

You will need to add documents which will assist the TGA in determining information about your ingredient. You can add up to three such documents. To add a document

Click on [Browse...](#)

This takes you to a Choose File format where you can select the appropriate document from your desktop.

Double click on the document name. This will take the document and place it in the Australian Device Name Nomination Form.

When you have completed filling out the form, you should print off a copy for your records.

Click on  Print

And follow the prompts to print a copy of the Australian Device Name Nomination Form.

If you are satisfied with the information you have added to the form,

Click on  Send

This will take you back to page 3A Medicated or Formulated.

You will receive an e-mail from the TGA advising that your application for a new ingredient has been received.

If you have more than one new ingredient, you will need to repeat the above New Ingredient process.

At this point, you should  Save and  Close your application. Until the new ingredient details are acknowledged by the TGA, you will not be able to submit the application. You should receive an e-mail from the TGA confirming the receipt of your New Ingredient details.

Take note of your Application Identifier Number for accessing your draft application once your new ingredient has been included on the TGA database.

At a later date you will receive an e-mail from the TGA advising that the ingredient name is available for use in your Class 1 application. Once you receive this information, you can complete your Device Application.



TGA

THERAPEUTIC GOODS ADMINISTRATION



Device Application - Page 4A

If you have answered YES to any question relating to your device containing a medicine that is supplied separately in Australia, you will see the following screen.

★ Does the product contain a medicine that is supplied separately in the Australian Market:

 Yes No

Procedure Pack or System Components Australian Market

TGA eBS Device Application

[Previous](#) [Next](#) [Close](#) [Save](#) [View Entire App](#) [Validate](#)

Application Identifier: DV-2008-DA-56369-3

Page 4A - Procedure Pack or System Components Australian Market
Enter details of each component that is a medicine supplied separately on the Australian Market.

★ Component Description:

★ Component ARTG Number:

[Add](#)

Component List

#	Component Description	ARTG Num.	Animal Species.	Country.

To remove item number from list:

Developing a Component List

At **Component Description**

Type in the description of the component

And at **Component ARTG Number:**

Type in the ARTG Number for the component

When you have entered the required information

Click on [Add](#)

This will take your component and add it to the Component List.

Continue this sequence until all components are listed.



TGA

THERAPEUTIC GOODS ADMINISTRATION



If you make a mistake or need to remove a line item, at

[To Remove item number from list](#)

Click on the drop down list



Point to and click on the line number of the item that needs to be removed,

Click on



This will remove the line item concerned.

Once you are satisfied with your Ingredient List

Click on



How you have answered questions on page 1 will determine which screen is presented next.



TGA

THERAPEUTIC GOODS ADMINISTRATION



Device Application Page 4b

If you have answered YES to any question relating to your device

a. Having content of animal origin

And / Or

b. Incorporates a medicine as an integral part and that has an action ancillary to the device

you will be presented with Page 4b – Procedure Pack or System components Ancillary.

★ Does any component in the procedure pack, kit or system contain material or ingredients of Animal Origin rendered non-viable?* Yes No

*If 'Yes' please enter the animal origin details for each relevant component on page 4b

★ Does the product contain a medical device which incorporates a medicine as an integral part and that has an action ancillary to the device? Yes No

Procedure Pack or System Components Ancillary

TGA eBS Device Application

Page 4B - Procedure Pack or System Components Ancillary
Enter details of each component that is a medical device which incorporates a medicine as an integral part and that has an action ancillary to the device.

★ Component Description:

- Animal Species:
- Country of Origin:

Add

Component List

#	Component Description	ARTG Num.	Animal Species	Country.
---	-----------------------	-----------	----------------	----------

Developing a Component List

At [Component Description](#)

Type in the description of the component making up the device.

From the drop down list

Select the [Animal Species](#):

And

Select the [Country of Origin](#)

When you have entered the required information

Click on **Add**

This will take your component and add it to the Component List.

Continue this sequence until all components are listed.



TGA

THERAPEUTIC GOODS ADMINISTRATION



If you make a mistake or need to remove a line item, at

[To Remove item number from list](#)

Click on the drop down list



Point to and click on the line number of the item that needs to be removed,

Click on [Remove](#)

This will remove the line item concerned.

Once you are satisfied with your Ingredient List

Click on [Next](#)

This takes you to Page 5 of the Device Application process.



TGA

THERAPEUTIC GOODS ADMINISTRATION



Device Application - Page 5

Applicant's Certification

Applicant's Certification is where you are required to agree to the conditions relating to your device and your application. You should read the declaration carefully and ensure the information you have provided is true and correct.

TGA eBS Device Application

Previous Close Save View Entire App Validate Continue

Page 5 - Applicant's Certification

Application Identifier: DV-2008-DA-56901-3

Application ID:	DV-2008-DA-56901-3
Submission date:	16/09/2008
Application for:	Medical Device - Included
Application type:	Included
Sponsor name:	TGA Demo A
Agent name:	TGA Demo A
Sponsor own reference:	Enter Sponsor Own Reference Here
Device class:	Class 1 Sterile
Unique product identifier:	
Manufacturer name:	Cipan (Portugal)[22619]
Manufacturer address:	Vala do Carregado Alenquer Lisbon 2580 Portugal S [57590]
New manufacturer name:	
New manufacturer address:	
GMDN description:	Dressing, roll gauze[35017]
Intended purpose:	This intended purpose is for demonstration purposes
Manufacturer certificate ID:	DV-2008-MC-66684-3 - Manufacturer Evidence (Demonstration for All Classes)
System name:	

Device Application Applicant's Certification

At the top of the page, you will find a number of your application details including:

Application ID :	
Submission date :	
Application for:	
Application type:	
Sponsor name:	
Agent name:	
Sponsor own reference :	
Device class:	
Unique product identifier:	
Manufacturer name:	
Manufacturer address:	
New manufacturer name:	
New manufacturer address:	
GMDN description:	
Intended purpose	
Manufacturer certificate ID :	
System name:	

Check that the details are correct before proceeding.

If you have made a mistake or the details are incorrect, you will need to go back to make any changes. To go back

Click on

Previous

To take you back to any previous pages.



TGA

THERAPEUTIC GOODS ADMINISTRATION

Attaching Supporting Documentation

You must attach an electronic copy of the supporting documentation relating to your device for Included Medical Device – Class III/AIMD and Other Therapeutic Goods – Registered – other (i.e. human origin products). For other application types/classes, it is optional to attach an electronic copy of the supporting documentation relating to your device.

[Function to attach/add supporting information](#)

To add the supporting information

Click on [Add](#)

This takes you to a File Upload screen where you must specify:

- the Type of Conformity Document you have relating to your device;
- And
- allows you to select the actual document from your own computer system.

At Document Type:

Select the document type from the drop down list

Click on [Browse...](#)

to select the actual document on your Desktop/Computer.

When you have selected your Document Type and have selected the relevant file from your computer,

Click on [Add](#)

This will take your selections back to page 5 of Device Application

If you make a mistake or need to make a different selection,
Click on [Remove](#)

This will return you to page 5 of the Device Application screen
where you can commence your search again.

You now need to carefully read the declaration.



TGA

THERAPEUTIC GOODS ADMINISTRATION



Validating Device Application

You should view and print the details of the entire document before you Validate. (*This further ensures the details entered are correct and keeps a copy for your file*).

Click on **View Entire App**

Check the details on the screen. If they are all OK

Click on **Print**

And follow the prompts to print the form and keep for your reference.

Click on **Edit**

To return to page 5 of Device Application.

You now need to carefully read the declaration.

Once you are satisfied that all the information is correct, you will need to agree to the declaration by clicking on the Yes button

I agree

Yes

No

And you can now validate the application.

Click on **Validate**

If you have made a mistake or have missed filling a required field, the form will not validate. At the top of the screen a message will advise on the missing fields. For example:

You have not entered the Intended Purpose of use

You have not agreed to the declaration

You will need to go back and complete or correct the information before you can proceed. You can return to the relevant page by either clicking on the missed validation message or clicking on the previous button.

Successful completion of the Device Application form will return

Validation Successful at the top of the screen.

This last screen (Page 5) completes the sequence of screens presented for an Application for a Medical Device.

If the application type selected does not have an associated application fee

Click on **Submit** and the system will show a confirmation message.

If the application type selected has an associated application fee

Click on **Continue**

**TGA**

THERAPEUTIC GOODS ADMINISTRATION

This takes you to the Tax Invoice Screen.

Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

ABN: 40 939 406 804

Print Invoice and Submit application before closing the browser window.
[Return to Application](#) [Print](#) [Submit](#)

TGA Demo A

Customer No.		Enquiries	Phone	Fax	Contact Email Address
51122		TGA Revenue Department	(02) 6232 8228	(02) 6232 8222	TGA.Account@health.gov.au
Identifier	Description		Unit Price	GST	Total
DV-2008-DA-56901-3	Medical Device - Included		\$760.00	0.00	\$760.00
Application fees are exempt from GST under Division 81 of A New Tax System (Goods & Services Tax) Act 1999			Subtotal	\$760.00	
			GST	\$0.00	
			Total	\$760.00	

PAYMENT OPTIONS

ON-LINE PAYMENT OPTION

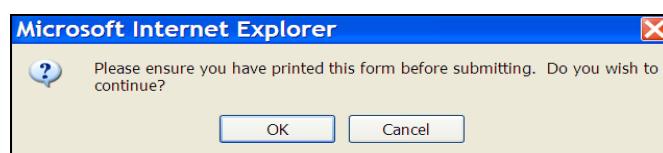
Credit card and Direct Debits may be paid on-line at:

Click on [Print](#)
To print a copy of the Tax Invoice.

If you make a mistake or need to make a change,
Click on [Return to Application](#)
This will return you to Device Change Request validated screen where you can make any necessary amendments.

Once you are happy with your details, and have printed the Tax Invoice,
Click on [Submit](#)

You will again be warned to print the Tax Invoice.



If you have printed the Tax Invoice,
Click on [OK](#)

The system will submit your Device Application and provide you with a confirmation similar to the following.

Device_51122, your Device Application DV-2008-DA-56901-3 has been submitted for processing.

Thank you

| [Home](#) |

Your device application (excluding any Included Medical Device – class 1 submissions) should appear in [View Lodged Submissions](#).



TGA

THERAPEUTIC GOODS ADMINISTRATION



VIEW DRAFTS Overview

If you have only partially complete entering details into one of your applications and then had to close the application, you will now need to get back into that application by using the View Drafts option of the TGA e-Business system.

You can access and update your draft submissions and applications via View Drafts.

This means that you can go into a partially completed submission or application, and complete it using this option.

When you login to the system, and select View Drafts, a list of all your current draft applications and submissions will be visible. The drafts will all have a minimum of the following information:

- Date (last accessed)
- Identifier (this is the unique identifier number created whenever you commence a submission or application.)
- Sponsor name

Depending on the level of detail already entered into your draft application or submission, additional information may be visible in the fields:

- Client Reference; (the reference you have entered)
- Information (the manufacturer's name/details)

Keeping a record of your Unique Identification Number (which appears at the top of each submission or application you create), will assist you to quickly locate your drafted submission or application.



TGA

THERAPEUTIC GOODS ADMINISTRATION



VIEW DRAFTS

Select [Portal – Therapeutic Goods Administration](#)

When the screen drops down

Click on the [View Drafts](#) option

TGA eBusiness

▼ Portal - Device Demo

- [View Drafts](#) ←
- [View Lodged Submissions](#)
- [Portal Help](#)
- ▶ [Create Applications & Submissions](#)
- ▶ [Lodge Supporting Documentation](#)
- ▶ [Maintain User Account](#)
- ▶ [TGA Information](#)
- ▶ [Accepted Manufacturer Information](#)
- [Accepted Medical Device Evidence](#)
- [SOLETRADE](#)
- [Sponsor Cancellation](#)
- [Online Invoice Payment](#)
- ▶ [News](#)
- ▶ [Help](#)
- ▶ [Training](#)
- [Logout](#)

Identifying your Draft Submission or Application

If you have a number of draft applications/submissions in the system, you will need to be able to find and identify it. The TGA e-Business system provides a number of means to enable you to do this.

Printing a list of your Draft Submissions and Applications

It's sometimes easier to look through your list from a paper copy. If you would like a paper copy of your Draft lists, you can print one.
At the top of the screen you will see the following:

Print	Refresh	First	1	2	3	4	5	6	7	8	9	Final
Viewing 210 of 210 entries: Page 7 of 9												

Click on [Print](#)

This will bring up a preview screen identifying your Draft Submissions and Applications.

Click on [Print](#) || [C](#)

Which is found at the top of the preview screen and follow the prompts to print your list.

Click on **Close**

To close the pop up screen.

Scrolling through View Drafts list

You can use the usual scroll bar to scroll up and down the list of your Draft Applications/Submission on the visible page. If you however need to search further, there are page selection buttons at the top of the screen.

Print Refresh First 1 2 3 4 5 6 7 8 9 Final
Viewing 210 of 210 entries: Page 7 of 9

Clicking on the particular number will take you directly to that page number where you can use the scroll bar to scroll up and down that page.

The **First** and **Final** button will take you either to the first page, or to the final page of your Draft list.

Searching for your Draft Submission or Application

Once you have selected View Drafts

The system provides a list of all your current draft applications and draft submissions. These appear in the following format.



TGA eBusiness Services



Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

Portal - Device Demo
Print Refresh First | Final

View Drafts
View Logged Submissions

Portal Help
Create Applications & Submissions

Lodge Supporting Documentation
Maintain User Account

TGA Information
Accepted Manufacturer Information

Accepted Medical Device Evidence
SOLETRADE

Sponsor Cancellation
Online Invoice Payment

News
Help

Training
Logout

Drafts

Approval Area:
Sponsor:

Search on:
for:
Reset All

Date	Identifier	Client Reference	Information	Sponsor
4	2008-09-16 DV-2008-MC-56884-3	: Manufacturer Evidence (Demonstration for All Classes)	Copan (Portugal)[22619]	TGA Demo A
4	2008-09-16 DV-2008-DA-56900-3	: Enter your own reference here	Copan (Portugal)[22619]	TGA Demo A
4	2008-09-15 DV-2008-MC-56875-3	: Enter your own reference here	7 Med Industrie (France)[50033]	TGA Demo A
4	2008-09-15 DV-2008-MC-56885-3	: Manufacturer Evidence (Demonstration MD/OTG)	Harmed Medical (Harwill Medical) (South Africa)[27919]	TGA Demo A
4	2008-09-11 DV-2008-MC-56825-3	: Demo	Mustang Industrial Corporation (Taiwan, Republic of China)[22263]	TGA Demo A
4	2008-09-11 DV-2008-DA-56827-3	test		TGA Demo A
4	2008-09-11 DV-2008-DA-56836-3	Test		TGA Demo A

Search options

There are a number of other means by which you can search for your draft submission or application. Broadly, you can

- filter using drop down lists; or
- sort by using column headings

Field Search options

You can undertake a number of field search options including filtering by:
Approval Area:

Sponsor: or
Search On / For

Approval Area:	All Approval Areas	<input type="button" value="Reset All"/>
Sponsor:	All Sponsors	<input type="button" value="Reset All"/>
Search on:	Date for <input type="text"/>	<input type="button" value="Reset All"/>

At **Approval Area**: you can select the following from the drop down list

Approval Area:	All Approval Areas	<input type="button" value="Reset All"/>
Sponsor:	All Approval Areas	<input type="button" value="Reset All"/>
Search on:	Date for <input type="text"/>	<input type="button" value="Reset All"/>

At **Sponsor** – The drop down screen provides a list of your sponsors. You can filter for application(s) using one of these Sponsors

Sponsor:	All Sponsors	<input type="button" value="Reset All"/>
Search on:	All Sponsors	<input type="button" value="Reset All"/>
Date	TGA Demo Spo	

Search on: The options available for devices allows you to narrow your search to:

- A specific date;
- The Application Identifier number;
- A Client reference you have used;
- A Manufacturer (at Information);
- The Class of your application; or
- (- The Status of your application does not relate to medical devices)

Search on:	Date for <input type="text"/>	<input type="button" value="Reset All"/>
	Date	
	Identifier	
<input type="checkbox"/>	2008-0 Client Reference	Client Reference
	Information	Manufacturer Evidence (Demonstration
<input type="checkbox"/>	2008-0 Class	All Classes)
<input type="checkbox"/>	2008-0 Status	Cipan (

An example of the specific search might be:

Click on **Identifier**

You know that the application you are searching for is for a Conformity Assessment (CA)

Type **CA** in the for field

This automatically lists all your current draft Conformity Assessment applications.



TGA

THERAPEUTIC GOODS ADMINISTRATION



Drafts

Approval Area: **All Approval Areas**

Sponsor: **All Sponsors**

Search on: **Identifier** for **mc** **Reset All**

Date	Identifier	Client Reference
<input type="checkbox"/>	2008-09-16 DV-2008-MC-56684-3	: Manufacturer Evidence (Demonstration for All Classes) Cipan (Por
<input type="checkbox"/>	2008-09-15 DV-2008-MC-56875-3	: Enter your own reference here 7 Med Indu
<input type="checkbox"/>	2008-09-15 DV-2008-MC-56685-3	: Manufacturer Evidence (Demonstration IVD/OTG) Harmed M
<input type="checkbox"/>	2008-09-11 DV-2008-MC-56825-3	: Demo

Column Search Option

This is a very interactive option, you simply point and click on the preferred column heading. For Example, if you click on the Column heading 'Date' it will sort all the draft applications/submissions in either ascending or descending order.

If you Click on the

Reset All button

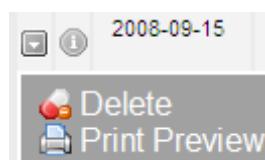
All the draft applications and submissions will be re-listed enabling you to start a fresh search.

Information Buttons and

To the left hand side of the View Drafts list you will see the and buttons.

Click on

This will bring up a range of options including
Copying the Application
Deleting the Application
Print Preview (and Print) the Application



Click on

This brings up an application status mini screen similar to the following.

Identifier	DV-2008-DA-56836-3
Sponsor	TGA Demo A
Type	Included
Class	Class 1
Contact	Device Demo
Form	DEVAPPCLAS1



TGA

THERAPEUTIC GOODS ADMINISTRATION



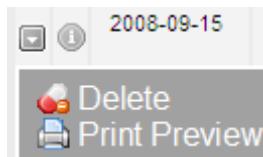
At a glance it gives you a range of information about the application. This can help you to determine whether this is the application you are in fact searching for.

Deleting a Draft

When you

Click on

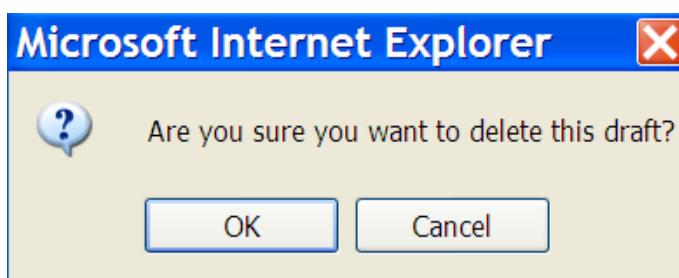
You are presented with the following options



If you would like to delete an application, find the application you wish to delete and

Click on

The following warning appears



If you are sure that this is the application you wish to delete

Click on

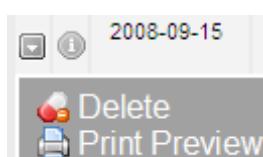
This deletes the application and removes the item from View Drafts.

Print Preview a Draft (Not including Request Change)

When you

Click on

You are presented with the following options



If you would like to print information regarding the application,

Click on

This will bring up a window similar to the following.

A A

Device Application

Application Details

Application Identifier:	DV-2008-DA-56836-3
Application for:	Medical Device - Included
Sponsor's own Reference:	Test

Sponsor Details

Agent Name:	TGA Demo A
Sponsor ID:	51122
Sponsor Name:	TGA Demo A
Contact Details:	Device Demo
Contact Email:	Devicedemo@tga.com.au

Device Details

Class:	Class 1
Intended Purpose:	

Specific Details

Is the device, or any form of the device, supplied sterile: Sterilisation Method:	No
Is the device intended to be invasive:	
Is the device, or any form of the device, intended for single use:	No
Is the device an active device:	No
Does the device contain material or ingredients of microbial origin:	
Does the device contain material or ingredients of recombinant origin:	No
Does the device contain material or ingredients manufactured or formulated using a genetically modified organism:	

To Print the details of this screen

Click on **Print**

Found at the top right hand of the pop up screen and follow the prompts to print the application details.

Once you have printed the application details,

Click on **Close**

To close the pop up screen.

Selecting your draft application/submission

Once you have searched for and found the draft application/submission you were looking for, simply **point to and click on** that application/submission.

This opens up the application enabling you to continue to work on or complete your application/submission.



TGA

THERAPEUTIC GOODS ADMINISTRATION



View Lodged Submissions

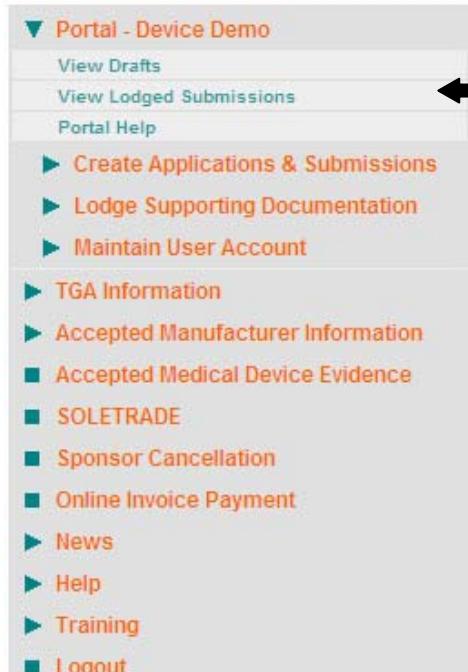
The View Lodged Submissions screen allows you to view the status of an Application/Submission you have lodged with the TGA.

Select [Portal – Therapeutic Goods Administration](#)

When the screen drops down

Click on the [View Lodged Submissions](#) option

TGA eBusiness



This takes you to a list of all your submitted Applications/Submissions.

Change Requests; and
Included Medical Device – Class 1
will not appear in this list.

Searching for your Lodged Submission or Application

Once you have selected [View Lodged Submissions](#)

The system provides a list of all your current ‘active’ applications and submissions. These appear in a similar format to the following.

TGA eBusiness Services

▼ Portal - Device Demo

- [View Drafts](#)
- [View Lodged Submissions](#)
- [Portal Help](#)
- [Create Applications & Submissions](#)
- [Lodge Supporting Documentation](#)
- [Maintain User Account](#)
- [TGA Information](#)
- [Accepted Manufacturer Information](#)
- [Accepted Medical Device Evidence](#)
- [SOLETRADE](#)
- [Sponsor Cancellation](#)
- [Online Invoice Payment](#)
- [News](#)
- [Help](#)
- [Training](#)
- [Logout](#)

Submissions

Approval Area:

Sponsor:

Search on: for

Received	Identifier	Workflow Status	Description
2008-09-16	DV-2008-DA-56801-3	Submitted	Enter Sponsor Own Reference Here
2008-09-16	DV-2008-CA-56894-3	Submitted	Enter your own reference here

If you have a number of Applications/Submissions lodged with TGA, you will need to be able to find and identify it. The TGA e-Business system provides a number of means to enable you to do this.

Printing a list of your Lodged Submissions and Applications

It's sometimes easier to look through your list from a paper copy. If you would like a paper copy of your Lodged Submissions, you can print one. At the top of the screen you will see the following:

<input type="button" value="Print"/>	<input type="button" value="Refresh"/>	<input type="button" value="First"/>	<input type="button" value="1"/>	<input type="button" value="2"/>	<input type="button" value="Final"/>
--------------------------------------	--	--------------------------------------	----------------------------------	----------------------------------	--------------------------------------

Viewing 39 of 39 entries: Page 1 of 2

Click on

This will bring up a preview screen identifying your Lodged Submissions and Applications.

Click on

Which is found at the top of the preview screen and follow the prompts to print your list.

Click on

To close the pop up screen.

Scrolling through View Drafts list

You can use the usual scroll bar to scroll up and down the list of your Lodged Applications/Submission on the visible page. If you however need to search further, page selection buttons at the top of the screen.

<input type="button" value="Print"/>	<input type="button" value="Refresh"/>	<input type="button" value="First"/>	<input type="button" value="1"/>	<input type="button" value="2"/>	<input type="button" value="Final"/>
--------------------------------------	--	--------------------------------------	----------------------------------	----------------------------------	--------------------------------------

Viewing 39 of 39 entries: Page 1 of 2



TGA

THERAPEUTIC GOODS ADMINISTRATION



Clicking on the particular number will take you directly to that page number where you can use the scroll bar to scroll up and down that page.

The **First** and **Final** button will take you either back to the first page, or to the final page of your Lodged Submissions.

Search options

There are a number of other means by which you can search for your Lodged Submission or Application. Broadly, you can

- filter using drop down lists; or
- sort by using column headings

Field Search options

Field Search areas include by:

Approval Area:

Sponsor: or

Search On / For

Approval Area:	All Approval Areas	▼
Sponsor:	All Sponsors	▼
Search on:	Date	▼ for []
Reset All		

At Approval Area: you can select the following from the drop down list.

Approval Area:	All Approval Areas	▼
Sponsor:	All Approval Areas	▼
Search on:	Date	▼ for []
Reset All		

At Sponsor – The drop down list provides a list of your sponsors. You can search for application(s) using one of these Sponsors

Sponsor:	All Sponsors	▼
Search on:	All Sponsors	▼
	TGA Demo A	
	Date TGA Demo Spo	

The search on: option allows you to narrow your search to:

Received (Date received by TGA)

Identifier (the Unique Application Identifier number)

Workflow Status (Whether it is under review or just submitted)

Description (Of the Device)

Product Name (If you have given it one)

Search on:	Received	▼
Rec	Received	▼
200	Identifier	
16	Workflow Status	
	Description	
	Product Name	

An example of the specific search might be:

Click on **Identifier**

You know that the application you are searching for is for a Device Application (DA)

Type **DA** in the for field

This automatically lists all your Lodged Device Applications

Submissions

Submissions					
Approval Area:		Sponsor:		Search on:	
All Approval Areas		All Sponsors		Identifier	for <input type="text" value="Da"/>
Received		Identifier	Workflow Status	Description	Product Name
2008-09-16	2008-09-16	DV-2008-DA-56901-3	Submitted	Enter Sponsor Own Reference Here	
2008-09-16	2008-09-16	DV-2008-DA-56899-3	Submitted	t	

Viewing 2 of 3 entries: Page 1 of 1

Column Search Option

This is a very interactive option, you simply point and click on the preferred column heading. For Example, if you click on the Column heading 'Date' it will sort all the Lodged Applications/Submissions in either ascending or descending order.

If you

Click on the button

All the draft applications and submissions will be re-listed enabling you to start a fresh search.

Information Buttons and

To the left hand side of the View Drafts list you will see the  and  buttons.

Click on 

This brings up a mini information screen which provides some details about the particular Application/Submission. The screen is similar to the following.

Identifier	DV-2008-DA-56901-3
Status	I
Type	Included
Class	CLAS1S
Contact	Device Demo
Manufacturer	Cipan (Portugal)[22619]
Form	DEVAPP

If you wish to retrieve more information than that provided in the Mini Screen

Click on 

This gives you the print preview option

If you click on  Print Preview

This will bring up a window similar to the following.

A / A Print | Close

Device Application TGA eB 

Application Details

Application Identifier: DV-2008-DA-56901-3
 Application for: Medical Device - Included
 Sponsor's own Reference: Enter Sponsor Own Reference Here

Sponsor Details

Agent Name: TGA Demo A
 Sponsor ID: 51122
 Sponsor Name: TGA Demo A
 Contact Details: Device Demo
 Contact Email: Devicedemo@tga.com.au

Device Details

Class: Class 1 Sterile
 Intended Purpose: done

Specific Details

Is the device, or any form of the device, supplied sterile: Yes
 Sterilisation Method:



To Print the details of this screen

Click on Print

Found at the top right hand of the pop up screen and follow the prompts to print the application details.

Once you have printed the application details,

Click on Close

To close the pop up screen.